LEADERSHIP Attributes

What it will take to help your organization succeed

PLUS:

DRUG PRICING TOOLS

IMPROVE DATA USE

BOOST PATIENT SATISFACTION

Special Report
Seven Ways to Reduce Readmissions
YES CAR T IS HERE

YESCARTA®, THE FIRST CAR T THERAPY FOR CERTAIN TYPES OF RELAPSED OR REFRACTORY LARGE B-CELL LYMPHOMA

The following data reflect results from the ZUMA-1 pivotal trial†

**PROVEN EFFICACY**

51%

Patients achieved a best response of complete remission (CR) (52/101)

NR

Response duration was not reached at a median follow-up of 7.9 months in patients who achieved CR

**CYTOKINE RELEASE SYNDROME**

13% 94%

Grade ≥3 incidence Overall incidence

**NEUROLOGIC TOXICITIES**

31% 87%

Grade ≥3 incidence Overall incidence

**RAPID & RELIABLE MANUFACTURING**

17 DAYS

Median turnaround time†

99%

Manufacturing success of CAR T cells engineered and expanded ex vivo

VISIT YESCARTAHCP.COM/CENTERS TO FIND A LIST OF AUTHORIZED TREATMENT CENTERS

*ZUMA-1 was an open-label, single-arm study in 101 adult patients who received YESCARTA® therapy. Patients received lymphodepleting chemotherapy prior to a single infusion of YESCARTA® at a target dose of 2 x 10⁶ viable CAR T cells/kg body weight (maximum of 2 x 10⁸ viable CAR T cells). Patients had refractory disease to their most recent therapy, or had relapsed within 1 year after autologous hematopoietic stem cell transplantation.

†The median time from leukapheresis to product delivery.

**INDICATION**

YESCARTA® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Limitation of Use: YESCARTA® is not indicated for the treatment of patients with primary central nervous system lymphoma.

**IMPORTANT SAFETY INFORMATION**

BOXED WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA®. Do not administer YESCARTA® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA®, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA®. Provide supportive care and/or corticosteroids as needed.

- YESCARTA® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA® REMS.

Important Safety Information continued on adjacent page.
IMPORTANT SAFETY INFORMATION (continued)

CYTOKINE RELEASE SYNDROME (CRS): CRS occurred in 94% of patients, including 13% with ≥ Grade 3. Among patients who died after receiving YESCARTA®, 4 had ongoing CRS at death. The median time to onset was 2 days (range: 1-12 days) and median duration was 7 days (range: 2-58 days). Key manifestations include fever (78%), hypotension (41%), tachycardia (28%), hypoxia (22%), and chills (20%). Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome. Ensure that 2 doses of tocilizumab are available prior to infusion of YESCARTA®. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for 4 weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab or tocilizumab and corticosteroids as medically indicated.

NEUROLOGIC TOXICITIES: Neurologic toxicities occurred in 87% of patients. Ninety-eight percent of all neurologic toxicities occurred within the first 8 weeks, with a median time to onset of 4 days (range: 1-43 days) and a median duration of 17 days. Grade 3 or higher occurred in 31% of patients. The most common neurologic toxicities included encephalopathy (57%), headache (44%), tremor (31%), dizziness (21%), aphasia (18%), delirium (17%), insomnia (9%) and anxiety (9%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events including leukoencephalopathy and seizures occurred with YESCARTA®. Fatal and serious cases of cerebral edema have occurred in patients treated with YESCARTA®. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of neurologic toxicities. Monitor patients for signs or symptoms of neurologic toxicities for 4 weeks after infusion and treat promptly.

YES CARTA® REMS: Because of the risk of CRS and neurologic toxicities, YESCARTA® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA® REMS. The required components of the YESCARTA® REMS are: Healthcare facilities that dispense and administer YESCARTA® must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of 2 doses of tocilizumab are available for each patient for infusion within 2 hours after YESCARTA® infusion, if needed for treatment of CRS. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer YESCARTA® are trained about the management of CRS and neurologic toxicities. Further information is available at www.YESCARTAREMS.com or 1-844-454-KITE (5483).

HYPERSENSITIVITY REACTIONS: Allergic reactions may occur. Serious hypersensitivity reactions including anaphylaxis may be due to dimethyl sulfoxide (DMSO) or residual gentamicin in YESCARTA®.

SERIOUS INFECTIONS: Severe or life-threatening infections occurred. Infections [all grades] occurred in 38% of patients, and in 23% with ≥ Grade 3. Grade 3 or higher infections with an unspecified pathogen occurred in 16% of patients, bacterial infections in 9%, and viral infections in 4%. YESCARTA® should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after YESCARTA® infusion and treat appropriately. Administer prophylactic anti-microbials according to local guidelines. Febrile neutropenia was observed in 36% of patients and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids and other supportive care as medically indicated. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

PROLONGED CYTOPENIAS: Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and YESCARTA® infusion. Grade 3 or higher cytopenias not resolved by Day 30 following YESCARTA® infusion occurred in 28% of patients and included thrombocytopenia (18%), neutropenia (15%), and anemia (3%). Monitor blood counts after YESCARTA® infusion.

HYPOGAMMAGLOBULINEMIA: B-cell aplasia and hypogammaglobulinemia can occur. Hypogammaglobulinemia occurred in 15% of patients. Monitor immunoglobulin levels after treatment and manage using infection precautions, antibiotic prophylaxis and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following YESCARTA® treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during YESCARTA® treatment, and until immune recovery following treatment.

SECONDARY MALIGNANCIES: Patients may develop secondary malignancies. Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Due to the potential for neurologic events, including altered mental status or seizures, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following YESCARTA® infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

ADVERSE REACTIONS: The most common adverse reactions [incidence ≥ 20%] include CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, infections-pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias.

Please see Brief Summary of Prescribing Information, including BOXED WARNING, on the following pages.
BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR YESCARTA® (axicabtagene ciloleucel) suspension for intravenous infusion

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA. Do not administer YESCARTA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids [see Dosage and Administration (2.2, 2.3), Warnings and Precautions (6.1)].

- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA. Provide supportive care and/or corticosteroids, as needed [see Dosage and Administration (2.2, 2.3), Warnings and Precautions (6.2)].

YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA REMS [see Warnings and Precautions (5.3)].

1 INDICATIONS AND USAGE

YESCARTA is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Limitation of Use: YESCARTA is not indicated for the treatment of patients with primary central nervous system lymphoma.

2 DOSAGE AND ADMINISTRATION

2.2 Administration: YESCARTA is for autologous use only. The patient’s identity must match the patient identifiers on the YESCARTA cassette and infusion bag. Do not infuse YESCARTA if the information on the patient-specific label does not match the intended patient [see Dosage and Administration (2.2, 2.3)].

Preparing Patient for YESCARTA Infusion: Confirm availability of YESCARTA prior to starting the lymphodepleting regimen. Pre-treatment: Administer a lymphodepleting chemotherapy regimen of cyclophosphamide 500 mg/m² intravenously and fludarabine 30 mg/m² intravenously on the fifth, fourth, and third day before infusion of YESCARTA. Premedication: Administer acetaminophen 650 mg PO and diphenhydramine 12.5 mg intravenously or PO approximately 1 hour before YESCARTA infusion. Avoid prophylactic use of systemic corticosteroids, as it may interfere with the activity of YESCARTA.

Preparation of YESCARTA for Infusion: Coordinate the timing of YESCARTA thaw and infusion. Confirm the thaw time in advance, and adjust the start time of YESCARTA thaw such that it will be available for infusion when the patient is ready. Confirm patient identity. Prior to YESCARTA preparation, match the patient’s identity with the patient identifiers on the YESCARTA cassette. Do not remove the YESCARTA product bag from the cassette if the information on the patient-specific label does not match the intended patient. Once patient identification is confirmed, remove the YESCARTA product bag from the cassette and check that the patient information on the cassette label matches the bag label. Inspect the product bag for any breaches of container integrity such as breaks or cracks before thawing. If the bag is compromised, follow the local guidelines (e.g., call Kite at 1-844-454-RITE). Place the infusion bag inside a second sterile bag per local guidelines. Thaw YESCARTA at approximately 37°C using either a water bath or dry thaw method until there is no visible ice in the infusion bag. Gently mix the contents of the bag to disperse clumps of cellular material. If visible cell clumps remain continue to gently mix the contents of the bag. Small clumps of cellular material should disperse with gentle manual mixing. Do not wash, spin down, and/or re-suspend YESCARTA in new media prior to infusion.

Administration: For autologous use only. Ensure that tocilizumab and emergency equipment are available prior to infusion and during the recovery period. Do NOT use a leukodepleting filter. Central venous access is recommended for the infusion of YESCARTA. Confirm the patient’s identity matches the patient identifiers on the YESCARTA product bag. Prime the tubing with normal saline prior to infusion. Infuse the entire contents of the YESCARTA bag within 30 minutes by either gravity or a perfusate pump. YESCARTA is stable at room temperature for up to 3 hours after thaw. Gently agitate the product bag during YESCARTA infusion to prevent cell clumping. After the entire content of the product bag is infused, rinse the tubing with normal saline at the same infusion rate to ensure all product is delivered. YESCARTA contains human blood cells that are genetically modified with replication incompetent retroviral vector. Follow universal precautions and local biosafety guidelines for handling and disposal to avoid potential transmission of infectious diseases.

Monitoring: Administer YESCARTA at a certified healthcare facility. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities. Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.

2.3 Management of Severe Adverse Reactions

Cytokine Release Syndrome (CRS): Identify CRS based on clinical presentation [see Warnings and Precautions (5.1)]. Evaluate for and treat other causes of fever, hypoxia, and hypotension. If CRS is suspected, manage according to the recommendations in Table 1. Patients who experience Grade 2 or higher CRS (e.g., hypotension, not responsive to fluids, or hypoxia requiring supplemental oxygenation) should be monitored with continuous cardiac telemetry and pulse oximetry. For patients experiencing severe CRS, consider performing an echocardiogram to assess cardiac function. For severe or life-threatening CRS, consider intensive care supportive therapy.

Table 1. CRS Grading and Management Guidance

<table>
<thead>
<tr>
<th>CRS Grade (a)</th>
<th>Tocilizumab</th>
<th>Corticosteroids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Administer tocilizumab (c) 8 mg/kg intravenously over 1 hour (not to exceed 800 mg). Repeat tocilizumab every 8 hours as needed if not responsive to intravenous fluids or increasing supplemental oxygen. Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses.</td>
<td>Manage per Grade 3 if no improvement within 24 hours after starting tocilizumab.</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Per Grade 2 Administer methylprednisolone 1 mg/kg intravenously twice daily or equivalent dexamethasone (e.g., 10 mg intravenously every 6 hours). Continue corticosteroids use until the event is Grade 1 or less, then taper over 3 days.</td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td>Per Grade 2 Administer methylprednisolone 1000 mg intravenously per day for 3 days; if improves, then manage as above.</td>
<td></td>
</tr>
</tbody>
</table>

(a) Lee et al 2014, (b) Refer to Table 2 for management of neurologic toxicity, (c) Refer to tocilizumab Prescribing Information for details

Neurologic Toxicity: Monitor patients for signs and symptoms of neurologic toxicities (Table 2). Rule out other causes of neurologic symptoms. Patients who experience Grade 2 or higher neurologic toxicities should be monitored with continuous cardiac telemetry and pulse oximetry. Provide intensive care supportive therapy for severe or life-threatening neurologic toxicities. Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis for any Grade 2 or higher neurologic toxicities.
### Table 2. Neurologic Toxicity Grading and Management Guidance

<table>
<thead>
<tr>
<th>Grading Assessment</th>
<th>Concise CRS</th>
<th>No Concise CRS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Grade 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no improvement within 24 hours after starting tocilizumab, administer dexamethasone 10 mg intravenously every 6 hours if not already taking other corticosteroids. Continue dexamethasone use until the event is Grade 1 or less, then taper over 3 days.</td>
<td>Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis.</td>
<td>Administer dexamethasone 10 mg intravenously every 6 hours. Continue dexamethasone use until the event is Grade 1 or less, then taper over 3 days.</td>
</tr>
</tbody>
</table>

| **Grade 3**        |             |                |
| Administer tocilizumab per Table 1 for management of Grade 2 CRS. | Administer dexamethasone 10 mg intravenously every 6 hours. Continue dexamethasone use until the event is Grade 1 or less, then taper over 3 days. | Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis. |

| **Grade 4**        |             |                |
| Administer tocilizumab per Table 1 for management of Grade 2 CRS. Administer methylprednisolone 1000 mg intravenously per day for 3 days and continue methylprednisolone 1000 mg intravenously per day for 2 more days; if improves, then manage as above. | Administer methylprednisolone 1000 mg intravenously per day for 3 days; if improves, then manage as above. | Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis. |

### 4 CONTRAINDICATIONS: None.

### 5 WARNINGS AND PRECAUTIONS

#### 5.1 Cytokine Release Syndrome (CRS)

CRS, including fatal or life-threatening reactions, occurred following treatment with YESCARTA. In Study 1, CRS occurred in 94% (101/108) of patients receiving YESCARTA, including = Grade 3 (Lee grading system) CRS in 13% (14/108) of patients. Among patients who died after receiving YESCARTA, four had ongoing CRS events at the time of death. The median time to onset was 2 days (range: 1 to 12 days) and the median duration of CRS was 7 days (range: 2 to 58 days). Key manifestations of CRS include fever (78%), hypotension (41%), tachycardia (28%), hypoxia (22%), and chills (20%). Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS) [see Adverse Reactions (6)]. Ensure that 2 doses of tocilizumab are available prior to infusion of YESCARTA. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS. Patients for signs or symptoms of CRS for 4 weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time [see Patient Counseling Information (17)]. At the first sign of CRS, institute treatment with supportive care, tocilizumab or tocilizumab and corticosteroids as indicated [see Dosage and Administration (2.3)].

#### 5.2 Neurologic Toxicities

Neurologic toxicities, that were fatal or life-threatening, occurred following treatment with YESCARTA. Neurologic toxicities occurred in 87% of patients. Ninety-eight percent of all neurologic toxicities occurred within the first 8 weeks of YESCARTA infusion, with a median time to onset of 4 days (range: 1 to 43 days). The median duration of neurologic toxicities was 17 days. Grade 3 or higher neurologic toxicities occurred in 31% of patients. The most common neurologic toxicities included encephalopathy (57%), headache (44%), tremor (31%), dizziness (21%), aphasia (18%), delirium (17%), insomnia (9%) and anxiety (9%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events including leukoencephalopathy and seizures occurred with YESCARTA. Fatal and serious cases of cerebral edema have been observed in patients treated with YESCARTA. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of neurologic toxicities. Monitor patients for signs or symptoms of neurologic toxicities for 4 weeks after infusion and treat promptly [see Management of CRS, including fatal or life-threatening CRS (2.3); Neurologic Toxicities (5.3)].

#### 5.3 YESCARTA REMS

Because of the risk of CRS and neurologic toxicities, YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA REMS [see Boxed Warning and Warnings and Precautions (5.1 and 5.2)]. The required components of the YESCARTA REMS are:

- Healthcare facilities that dispense and administer YESCARTA must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on hand immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within 2 hours after YESCARTA infusion, if needed for treatment of CRS.
- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer YESCARTA are trained about the management of CRS and neurologic toxicities.

Further information is available at www.YescartaREMS.com or 1-844-454-KITE (5483).

#### 5.4 Hypersensitivity Reactions

Allergic reactions may occur with the infusion of YESCARTA. Severe, serious, and life-threatening hypersensitivity reactions including anaphylaxis, may be due to dimethyl sulfoxide (DMSO) or residual gentamicin in YESCARTA.

#### 5.5 Serious Infections

Severe or life-threatening infections occurred in patients after YESCARTA infusion. In Study 1, infections (all grades) occurred in 38% of patients. Grade 3 or higher infections occurred in 23% of patients. Grade 3 or higher infections with an unspecified pathogen occurred in 16% of patients, bacterial infections in 19%, and viral infections in 4%. YESCARTA should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection and infection after YESCARTA infusion and treat appropriately. Administer prophylactic anti-microbials according to local guidelines. Febrile neutropenia was observed in 36% of patients after YESCARTA infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids and other supportive care as medically indicated. Viral Reactivation: Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

#### 5.6 Prolonged Cytopenias

Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and YESCARTA infusion. In Study 1, Grade 3 or higher cytopenias not resolved by Day 30 following YESCARTA infusion occurred in 26% of patients and included thrombocytopenia (16%), neutropenia (15%), and anemia (3%). Monitor blood counts after YESCARTA infusion.

#### 5.7 Hypogammaglobulinemia

B-cell aplasia and hypogammaglobulinemia can occur in patients receiving treatment with YESCARTA. In Study 1, hypogammaglobulinemia occurred in 15% of patients. Monitor immunoglobulin levels after treatment with YESCARTA and manage using infection precautions, antibiotic prophylaxis and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following YESCARTA treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during YESCARTA treatment, and until immune recovery following treatment with YESCARTA.

#### 5.8 Secondary Malignancies

Patients treated with YESCARTA may develop secondary malignancies. Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

#### 5.9 Effects on Ability to Drive and Use Machines

Due to the potential for neurologic events, including altered mental status or seizures, patients receiving YESCARTA are at risk for altered or decreased consciousness or coordination in the 8 weeks following YESCARTA infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

### 6 ADVERSE REACTIONS

The following adverse reactions are described in Warnings and Precautions: Cytokine Release Syndrome, Neurologic Toxicities, Hypersensitivity Reactions, Serious Infections, Prolonged Cytopenias, Hypogammaglobulinemia.

#### 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. The safety data described in this section reflect exposure to YESCARTA in the clinical trial (Study 1) in which 108 patients with relapsed/refractory B-cell NHL received CAR-positive T cells based on a recommended dose which was weight-based (see Clinical Trials (14)). Patients had a history of CNS disorders (such as seizures or cerebrovascular ischemia) or autoimmune disease requiring systemic immunosuppression were ineligible. The median duration of follow up was 8.7 months. The median age of the study population was 58 years (range: 23 to 76 years); 68% were men.
43% with ECOG 0, and 57% with ECOG 1. The most common adverse reactions
(incidence ≥ 20%) include CRS, fever, hypotension, encephalopathy, tachycardia,
fever, headache, decreased appetite, chills, diarrhea, febrile neutropenia,
infections-pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting,
dizziness, constipation, and cardiac arrhythmias. Serious adverse reactions occurred
in 52% of patients. The most common serious adverse reactions (> 2%) include
encephalopathy, fever, lung infection, febrile neutropenia, cardiac arrhythmia,
cardiac failure, urinary tract infection, renal insufficiency, aphasia, cardiac arrest,
Clostridium difficile infection, delirium, hypotension, and hypoxia. The most common
(≥ 10%) Grade 3 or higher reactions include febrile neutropenia, fever, CRS,
encephalopathy, infections-pathogen unspecified, hypotension, hypoxia, and lung
infections. Forty-five percent (49/108) of patients received tocilizumab after infusion
of YESCARTA.

Summary of Adverse Reactions Observed in at Least 10% of the Patients
Treated with YESCARTA in Study 1

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Any Grade (%)</th>
<th>Grades 3 or Higher (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tachycardia</td>
<td>57</td>
<td>2</td>
</tr>
<tr>
<td>Arthrythms</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>38</td>
<td>4</td>
</tr>
<tr>
<td>Nausea</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>26</td>
<td>1</td>
</tr>
<tr>
<td>Constipation</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>86</td>
<td>16</td>
</tr>
<tr>
<td>Fatigue</td>
<td>46</td>
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<tr>
<td>Chills</td>
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<tr>
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</tr>
<tr>
<td>Immune system disorders</td>
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<td></td>
</tr>
<tr>
<td>Cytokine release syndrome</td>
<td>94</td>
<td>13</td>
</tr>
<tr>
<td>Hypogammaglobulinemia</td>
<td>15</td>
<td>0</td>
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<tr>
<td>Infections and infestations</td>
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<td></td>
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<tr>
<td>Infections-pathogen unspecified</td>
<td>26</td>
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<tr>
<td>Viral infections</td>
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<td>Bacterial infections</td>
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<tr>
<td>Decreased appetite</td>
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<td>Weight decreased</td>
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<td>0</td>
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<tr>
<td>Dehydration</td>
<td>11</td>
<td>3</td>
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<tr>
<td>Musculoskeletal and connective tissue disorders</td>
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<tr>
<td>Motor dysfunction</td>
<td>19</td>
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<tr>
<td>Pain in extremity</td>
<td>17</td>
<td>2</td>
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<tr>
<td>Back pain</td>
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<td>Muscle pain</td>
<td>14</td>
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<td>Arthralgia</td>
<td>10</td>
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<tr>
<td>Nervous system disorders</td>
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<td></td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>57</td>
<td>29</td>
</tr>
<tr>
<td>Headache</td>
<td>45</td>
<td>1</td>
</tr>
<tr>
<td>Tremor</td>
<td>31</td>
<td>2</td>
</tr>
<tr>
<td>Dizziness</td>
<td>21</td>
<td>1</td>
</tr>
<tr>
<td>Aphasia</td>
<td>18</td>
<td>6</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delirium</td>
<td>17</td>
<td>6</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypoxia</td>
<td>32</td>
<td>11</td>
</tr>
<tr>
<td>Cough</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>19</td>
<td>3</td>
</tr>
<tr>
<td>Pleural effusion</td>
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<td>2</td>
</tr>
<tr>
<td>Renal and urinary disorders</td>
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<td></td>
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<tr>
<td>Renal insufficiency</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Vascular disorders</td>
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<td></td>
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<tr>
<td>Hypotension</td>
<td>57</td>
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</tr>
<tr>
<td>Hypertension</td>
<td>15</td>
<td>6</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>10</td>
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</tr>
</tbody>
</table>

The following events were also counted in the incidence of CRS, tachycardia, arrhythmia, fever, chills, hypoxia, renal insufficiency, and hypotension. For a complete list of events that contributed to the incidence of certain adverse reactions, please see footnotes Table 3 in Section 6.1 of the Full Prescribing Information.

Other clinically important adverse reactions that occurred in less than 10% of
patients treated with YESCARTA include the following: blood and lymphatic system
disorders: coagulopathy (2%); cardiac disorders: cardiac failure (6%) and cardiac
arrest (4%); immune system disorders: hemophagocytic lymphohistiocytosis/
macrophage activation syndrome (HLH/MAS) (1%), hypersensitivity (1%); infections
and infestations disorders: fungal infections (5%); nervous system disorders: ataxia
(6%), seizure (4%), dyscalculia (2%), and myoclonus (2%); respiratory, thoracic
and mediastinal disorders: pulmonary edema (9%); skin and subcutaneous tissue
disorders: rash (9%); vascular disorders: capillary leak syndrome (3%).

Grade 3 or 4 Laboratory Abnormalities Occurring in ≥ 10% of Patients
in Study 1 Following Treatment with YESCARTA based on CTCAE (N=108)

<table>
<thead>
<tr>
<th>Laboratory Value</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphopenia</td>
<td>100</td>
<td>97</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>96</td>
<td>93</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>93</td>
<td>66</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>56</td>
<td>50</td>
</tr>
<tr>
<td>Hypophosphatemia</td>
<td>50</td>
<td>10</td>
</tr>
<tr>
<td>Uric acid</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Direct Bilirubin</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Hyponatremia</td>
<td>23</td>
<td>19</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>10</td>
<td>5</td>
</tr>
</tbody>
</table>

6.2 Immunogenicity: YESCARTA has the potential to induce anti-product antibodies. The immunogenicity of YESCARTA has been evaluated using an enzyme-linked immunosorbent assay (ELISA) for the detection of binding antibodies against FMC63, the originating antibody of the anti-CD19 CAR. Three patients tested positive for pre-dose anti-FMC63 antibodies at baseline and Month 1, 3, or 6 in Study 1. There is no evidence that the kinetics of initial expansion and persistence of YESCARTA, or the safety or effectiveness of YESCARTA, was altered in these patients.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Risk Summary: There are no available data with YESCARTA use in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with YESCARTA to assess whether it can cause fetal harm when administered to a pregnant woman. It is not known if YESCARTA has the potential to be transferred to the fetus. Based on the mechanism of action, if the transduced cells cross the placenta, they may cause fetal toxicity, including B-cell lymphocytopenia. Therefore, YESCARTA is not recommended for women who are pregnant, and pregnancy after YESCARTA infusion should be discussed with the treating physician. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% - 4% and 15% - 20%, respectively.

8.2 Lactation: Risk Summary: There is no information regarding the presence of YESCARTA in human milk, the effect on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for YESCARTA and any potential adverse effects on the breastfed infant from YESCARTA or from the underlying maternal condition.

8.3 Females and Males of Reproductive Potential: Pregnancy Testing: Pregnancy status of females with reproductive potential should be verified. Sexually-active females of reproductive potential should have a pregnancy test prior to starting treatment with YESCARTA. Contraception: See the prescribing information for fludarabine and cyclophosphamide for information on the need for effective contraception in patients who receive the lymphodepleting chemotherapy. There are insufficient exposure data to provide a recommendation concerning duration of contraception following treatment with YESCARTA. Infertility: There are no data on the effect of YESCARTA on fertility.

8.4 Pediatric Use: The safety and efficacy of YESCARTA have not been established in pediatric patients.

8.5 Geriatric Use: Clinical trials of YESCARTA did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently or have different safety outcomes as compared to younger patients.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide). Ensure that patients understand the risk of manufacturing failure (1% in clinical trial). In case of a manufacturing failure, a second manufacturing of YESCARTA may be attempted. In addition, while the patient awaits the product, additional chemotherapy (not the lymphodepletion) may be necessary and may increase the risk of adverse events during the pre-infusion period. Advise patients to seek immediate attention for any of the following: Cytokine Release Syndrome, Neurologic Toxicities, Serious Infections, Prolonged Cytopenia [See Warnings and Precautions (5.1, 5.2, 5.3, 5.5) and Adverse Reactions (6) for more information and signs and symptoms]. Advise patients for the need to: Refrain from driving or operating heavy or potentially dangerous machinery after YESCARTA infusion until at least 8 weeks after infusion [See Warnings and Precautions (5.2)]. Have periodic monitoring of blood counts. Contact Kite at 1-844-454-KITE (5483) if they are diagnosed with a secondary malignancy [See Warnings and Precautions (5.8)].

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High-Value Leadership
Reimbursement shift drives new needs

A change is occurring, and it’s not the type of change we typically talk about in the shifting healthcare landscape. It is a change requiring us, as healthcare leaders, to acquire new skills, talents, and capabilities as we lead new and expanded teams of people in the treatment of patients.

Physician leaders, in particular, are trained well to do many things. We perform highly technical skills and complicated procedures. We manage multiple needs at the same time. We take an unstructured human narrative, break it down into individual components, and develop an entire care plan—determining if and when others are needed. We are trained well for one-to-one interactions with our patients. This training has made us very good at a certain type of leadership—one that is based on hierarchy and a top-down approach.

Unfortunately, this team dynamic and leadership style is not effective in a value-based reimbursement model, where better health outcomes for chronically-ill patients is the measure of success.

As physicians, we intellectually understand a team-based approach is not effective in a value-based reimbursement model, where better health outcomes for chronically-ill patients is the measure of success.

We have generally not integrated social determinants of health or social workers, or recognized the true need of behavioral health as part of physical health.

New style needed
Over the past decades, we’ve expanded whom we work with, but we haven’t fundamentally changed how the team functions to best support the care of the chronically ill.

“Over the past decades, we’ve expanded whom we work with, but we haven’t fundamentally changed how the team functions to best support the care of the chronically ill.”

Research from the NHS Institute for Innovation and Improvement shows that clinicians want to be led by clinicians. If physicians want to lead in the value-based world, we need to get a team working together to achieve something that’s superior to what we would have achieved on our own. How do we do that?

Encourage collaboration.
We must do more than identify contributors. We need to get better at bringing people together to work not just alongside each other, but with each other. This is a table stake. Care for a population requires the cross-pollination of multiple people with intersecting expertise.

Increase transparency. In the joint decision-making process, we must be willing to have difficult conversations with our peers and influential people within our organizations, realizing they may not be happy with us.

Practice humility. Assume other providers know more than we do on a large number of topics.

Be curious. Recognize the team has expertise; ask good questions and listen to what they are telling us.

Provide inspiration and motivation. How our team feels matters. They need to feel heard and that they have a purpose. Help them see the bigger picture and connect to meaning in their work.

Ultimately, the goals of healthcare are still the same. Our job is to improve health outcomes and help people achieve their best health. To do that, we must work together in new ways and, as leaders, we must change the way we lead.

High-Value Leadership
Reimbursement shift drives new needs

FROM ROY BEVERIDGE, MD, AND MEREDITH WILLIAMS, MD, MBA

Roy Beveridge, MD, is a Managed Healthcare Executive editorial advisor and Humana’s chief medical officer. Meredith Williams, MD, MBA, is lead medical director.
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What it will take to help your organization succeed

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by Roy Beveridge, MD, and Meredith Williams, MD, MBA

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45 THE BOTTOM LINE
Drugs are often considered a commodity but unlike other products, most people don’t know what they really cost. “We live in an era where you know the exact price of a car before you buy it and of a cab ride before you take it, but healthcare remains one of the few areas where there is still a need to lift the veil on drug pricing to patients,” says Richard Cohan, president, Patient Innovations Division, DrFirst, a Rockville, Maryland-based provider of medication management solutions.

In response to the lack of transparency, health organizations are creating tools that deliver patient-specific drug price information, helping physicians and pharmacists make more cost-effective decisions at the time of prescribing.

**Solutions for physicians**

In April, San Francisco-based Blue Shield of California and Gemini Health, a health IT firm in Sausalito, California, collaborated to launch the Drug–Cost Transparency Service. Matt Nye, PharmD, vice president of pharmacy services for Blue Shield, calls it a “real-time benefits tool.”

Operating through a provider’s EHR, the service displays information including:

- Patient out-of-pocket costs for selected medications based on a patient’s health plan benefits and formulary.
- Accurate total drug cost savings (based on actual payer costs and rebates) for up to three lower cost, dose-matched, clinically equivalent alternative medications.
- Total drug costs to the plan.
- Accurate patient cost and total savings for alternative pharmacies (e.g., specialty or mail order).
- Whether prior authorization is required, and/or alternative medications that don’t require it.
- Any coverage notices that would create pharmacy callbacks to the prescriber’s office.

“If we can provide patient-specific, accurate information at the point of prescribing—at the point of decision making—doctors will prescribe what is covered and is most effective,” Nye says. “An EHR needs to include decision support.”

He says the tool could lower out-of-pocket costs, reduce the need for medical office staff to check on prior authorization, and improve adherence.

As a physician, Edward J. Fotsch, MD, founder and CEO of Gemini Health, agrees that doctors don’t know the cost of drugs for patients when they prescribe them, though they would like to help patients lower their drug costs. “Doctors also would like to receive fewer callbacks from a pharmacy when they prescribe a drug requiring prior authorization or one that is too expensive,” he says.

The tool is available to Blue Shield of California’s network of physician groups at no cost, but members of other health plans using the same physician network can access the service through Gemini. Although no physicians are using the service at press time, as they are still working on EHR integration, Nye estimates that 30% to 40% will have access by the end of 2019.

**Solutions for pharmacists**

To keep drug costs in tow—especially for patients with high deductibles—CVS Health developed two new tools: the Pharmacy Rx Savings Finder and a real-time benefits program.

Recently launched in April, the real-time benefits program, similar to Blue Shield’s product, provides real-time, member-specific drug costs and up to five lower-cost alternatives based on a patient’s formulary. Prescribers receive the information through their EHRs. If prior authorization or step therapy is required, prescribers can immediately submit an electronic prior authorization request and in most cases, receive a near real-time decision. Members can access...
information through the member portal.

The other tool, the Pharmacy Rx Savings Finder, lets the company’s retail pharmacists evaluate individual prescription savings opportunities at the point of sale. Designed initially for CVS Caremark PBM members, the tool indicates:

- If a prescribed medication is on a patient’s formulary and if it is the lowest-cost option available.
- If there are lower-cost options covered under a patient’s pharmacy benefit, such as a generic medication or therapeutic alternative with equivalent efficacy of treatment.
- If a patient might be able to save money by filling a 90-day prescription rather than a 30-day one.
- Other potential savings options for eligible or uninsured patients if no generic or a lower-cost alternative is available.

“These tools help improve the patient experience and lower costs,” says Casey Leonetti, senior vice president of PBM innovation, CVS Health, “Specifically, they help avoid rejects at the pharmacy that can lead to primary non-adherence of required therapies; they save patients out-of-pocket costs by helping them maximize their drug benefit to find the lowest-cost option; and they reduce administrative burden and costs for providers and plans.”

Early results, according to CVS, show that prescribers accessing the information switched a patient’s drug from a noncovered drug to a drug on formulary 85% of the time, and when a patient’s drug was covered, prescribers switched the patient to a lower-cost alternative 30% to 40% of the time, saving an average of $75 to $100 per prescription.

Eight critical components of cost transparency tools

Lauren Vela, senior director of member value for the Pacific Business Group on Health in San Francisco, advocates for comprehensive and inclusive tools. She says it is critical to have:

1. Relevancy across multiple PBMs and health plans
2. Patient copayments
3. Plan cost
4. Cost/pricing information relevant to a patient’s preferred pharmacy
5. EHR integration
6. Ability to load a customized formulary, including rules, such as pre-authorization, step therapy, and exclusions
7. Value-priced alternatives with therapeutic dosing conversions
8. Reports identifying savings opportunities in existing prescriptions and alternative pharmacy options, if there are substantial pricing differences

“Doctors need more power and information about a drug, its effectiveness, and costs,” says Vela. “Without knowing the total cost of a drug, a doctor doesn’t know how much a plan or patient can save.”

Vela is concerned about waste in the healthcare system when higher-cost drugs with lower-price alternatives are prescribed. “Employers are spending money on higher-priced drugs that have lower-cost equivalents just because it is on formulary, and it’s on formulary because of incentives to PBMs,” she says.
Hospital CEO Keeps Pediatric Care Local

by TRACEY WALKER

Deborah Feldman, president and CEO of Dayton Children’s Hospital, has one goal in mind: “Keeping more of our children local for their care,” she says.

The hospital, the only pediatric one in the Dayton, Ohio, region, provides care for more than 300,000 children every year across 20 Ohio counties and eastern Indiana in a network of care facilities.

“Dayton Children’s has seen a significant increase in patients over the last several years despite being in a market which is demographically not growing,” says Feldman.

Upon joining the organization in 2012, she led the creation of Destination 2020, a strategic roadmap to guide the hospital into the rapidly changing future of healthcare.

Q: Managed Healthcare Executive (MHE): What is the biggest win that you have had at Dayton Children’s Hospital?

Feldman: We have been laser-focused on executing Destination 2020. The plan has four pillars: providing the exceptional patient experience, offering the right services, building strong physician integration between our pediatric subspecialists and our community pediatricians and family physicians, and developing positive care alliances between Dayton Children’s and other healthcare institutions, such as hospitals, medical schools, etc. Additionally, the plan includes four internal momentum builders: the right talent, modern technology, proactive culture, and financial vitality.

As a result of the plan, we identified key strategies including:

1/ The need to upgrade our facilities, resulting in a new patient tower and a new ambulatory destination center in our southern suburbs in 2017.

2/ The need to recruit more physicians to provide the right services for our community, resulting in more than 100 new pediatric subspecialists.

3/ Significantly expanding our mental health services to include a crisis assessment center and an inpatient unit.

4/ The development of a clinically integrated network with more than 100 of our local pediatricians.

5/ Building upon and adding new healthcare organizations as partners.

6/ Strengthening our culture through employee and physician engagement — both are now in the top decile of engagement.

Q: MHE: How has the ACA impacted your hospital?

Feldman: As a pediatric hospital, the protections that came with ACA have and continue to positively impact many of the children we care for. The elimination of life-time maximums and providing protection for those with pre-existing conditions for our privately insured families has been extremely beneficial. Although Ohio is a Medicaid expansion state, children in Ohio were already eligible for Medicaid up to 211% of the federal poverty level, covered by the combined Medicaid and CHIP. We did advocate strongly for Medicaid expansion because we recognized that the health of the entire family significantly impacts the health and well-being of children as well as impacting the long-term economic vitality of our state.

Q: MHE: How are you partnering with plans to address inappropriate use of the emergency department (ED)?

Feldman: ED utilization is a measure we are tracking closely through a shared savings program with Anthem. We are providing education about when to use ED versus PCP versus urgent care. We’re also working to delineate the best care pathways for kids with common diagnosis that end up in the ED. We’re developing programming to keep kids in the right setting of care, ideally getting the same high-quality treatment, when medically appropriate, from their PCP rather than a visit to the ED or specialist.
In 2020, more people living in Maine will be age 65 and older than the number of residents living there who aren’t seniors, according to the Bangor Daily News. The newspaper reports that this demographic shift is occurring 15 years ahead of U.S. Census Bureau projections, and similar demographic changes are taking place across the country.

That’s one of the reasons Brewer, Maine-based Eastern Maine Healthcare System, an integrated delivery network that includes acute care, medical-surgical hospitals, a psychiatric hospital, and other services, launched its Professional and Organizational Program in the summer of 2017. The goal of the program is to support and nurture current and emerging leaders by giving them the tools and knowledge they’ll need to bring the health system into the future.

“We want to continue to provide opportunities to our employees to gain additional training and knowledge to help prepare them for talent mobility,” says Catharine MacLaren, PhD, LCSW, vice president of talent and diversity. “This program teaches and enhances knowledge and practical skills aligned with accomplishing system goals and strategies.”

The program helps develop current employees, but MacLaren says it also has served as a recruitment tool during the hiring process.

How it works
The program lasts 11 months and includes two groups: a group of 50 leaders with direct reports and a group of 50 employees without direct reports. For both groups, employees have to apply and secure recommendations from their direct supervisor and two peers. All application materials are de-identified and ranked based on criteria that include examples of when the applicant has taken charge of their own career, what they offer to the program, and the impact of their work on their department. MacLaren says that while the program isn’t solely for younger employees, many of the participants are millennials.

Once accepted into the program, participants are split into teams of six or seven (they include both clinical and nonclinical participants) and are assigned an initiative that relates to the organization’s annual goals. At the end of the 11 months, teams present their recommendations to the health system. Each team is also assigned two to three executive sponsors, who are senior leaders and who help coach the teams.

The program is also a partnership with Husson University in nearby Bangor, which provides participants with six credits towards a master’s degree.

MacLaren, PhD, LCSW, vice president of talent and diversity, says, “This program teaches and enhances knowledge and practical skills aligned with accomplishing system goals and strategies.”

The program helps develop current employees, but MacLaren says it also has served as a recruitment tool during the hiring process.

What participants say

Executive sponsor
Iyad Sabbagh, MD
Sabbagh is system vice president and chief quality officer at the health system. Since program participants come from different backgrounds, “there are multiple types of experience around the table engaging in very constructive conversations and sharing ideas and respecting each other,” he says. Involving clinical and nonclinical team members in the program helps troubleshoot problems, he adds. For example, team members from the facilities department can learn from clinicians that a little bump in the floor can be challenging for elderly patients who can’t lift their legs.

Team member
Matthew Cummings
Cummings is a payroll operations analyst, who joined the program in October 2017. Cummings and his team are trying to determine the optimal way to educate employees about compliance with healthcare standards. His team plans to survey employees about their preference for online or in-person training with frontline managers.

“They’re giving me every opportunity to become a leader and find out what my dream job is,” says Cummings, who was recently accepted to a master’s program at Husson University.

Aine Cryts is a writer based in Boston.
The rapidly changing environment and new government mandates could dramatically impact the bottom line at healthcare organizations. That’s why Dennis Eder, MBA, MA, cofounder and managing partner of Strategic Health Group, a healthcare consultancy, says it’s crucial for healthcare leaders to possess an unprecedented level of flexibility. "Rigid adherence to any strategic or operating plan will significantly impair a plan’s options for success," he says.

Mary Herrmann, MS, managing director of executive coaching at BPI group, a leadership, talent, and career transition consultancy, agrees, noting that leaders need to be agile and easily adjust in ambiguous and deadline-driven situations. "They should be able to manage frequent changes, delays, and heavy workloads, and motivate and inspire their teams," she says. "In fact, they should excel under pressure."

It’s not just that leaders need to be flexible, they also need to be able to cultivate that attribute throughout their organizations, says Bill Fox, JD, MA, chief strategist of global healthcare, life sciences, and insurance at MarkLogic, an enterprise database company. They need to en-
sure that their organizations can pivot quickly in response to industry shifts.

While the rapidly changing environment requires leaders to be more agile and flexible than ever before, it’s also requiring them to improve in several other areas. Here are the attributes of highly effective healthcare leaders.

**POLICY SAVVY**

Some managed care organizations are growing their in-house policy experts so they can quickly shift directions depending on legislation. Blue Cross and Blue Shield of North Carolina, for example, recently hired a former Center for Medicare and Medicaid Innovation deputy administrator. “By employing these types of leaders, payers can better predict and get ahead of legislative changes,” says Ken Botsford, MD, chief medical officer at naviHealth, a care transitions and post-acute care management company.

In addition to cultivating a solid base of policy experts in-house, healthcare leaders need to hone their own policy skills, including building personal relationships with regulators at the state level, in particular with the Department of Insurance and the State Medicaid Agency, and appropriate personnel at CMS, says Eder. “We have seen clients, with the support and collaboration of other health plans, change significant proposed laws that would have affected their risk-based capital requirements.”

Cultivating personal relationships with federal and state legislators who represent the districts in which their organization operates is key, he says. “In short, it is not enough for the plan to be known; the plan’s face and voice needs to be known as well.”

Being able to speak to policymakers about the challenges facing their plan, and the industry in general, is also important, says Eder. Also, he says, leaders should be able to verbalize what policy changes would help achieve the Quadruple Aim, lower pharmaceutical costs, and address the aging population. “The more that leaders can do this, the more that policymakers will start to rely on health plan executives as a trusted source of unbiased information when health-related issues arise,” he says.

**SOCIAL MEDIA AWARENESS**

Social media presence can affect how customers and the competition perceive, relate to, and interact with a healthcare organization. That’s why executives must ensure their companies are fully utilizing it.

For example, patient engagement and wellness initiatives on social media pose an opportunity to reach consumers on an entirely different level and helps consumers recognize that a health plan is more than a medical claims processing organization, says Ashraf Shehata, MHA, principal at KPMG and a member of the tax, audit, and advisory firm’s Global Healthcare Center of Excellence. “They can educate patients without needing a big budget. Even if a few hundred people view a two-minute video pertaining to diabetes education, it can recoup the investment if it prevents a few hospitalizations.”

Fox says companies should engage in ongoing conversations with customers by monitoring customer posts and responding in a timely and meaningful manner to questions, concerns, or even compliments. That sends the message that meeting customers’ needs is a priority.

Healthcare executives should also use social media to build their knowledge base. For example, use it as a place to listen and gather information from customers and potential customers. “Learning about challenges from the patient’s perspective is often the best way to understand what healthcare consumers want and [how executives] need to reorient priorities,” Botsford says.

Another bonus of an active social media presence? It can help companies sense health epidemics faster, Fox says. For instance, people often use social media to share when they are not feeling well before they go to the doctor. An abnormal spike in such posts could indicate the start of the flu season in one area.

**TIPS FOR BURNED OUT EXECS**

You might have all the skills necessary to be a strong leader, but if you’ve lost your motivation and drive, none of that matters. If you’re feeling burned out, Carrie A. L. Arnold, PhD, principal coach and consultant at Denver-based The Willow Group, advises using yourself as a subject of study and determining your strengths, preferences, triggers, challenges, etc.

“When people are leveraging their strengths and preferences in an intentional way, they are less likely to lose their passion,” she says. “They are also able to make more intentional choices that help them recover when their energy wanes. I always recommend that leaders take all the assessments they can get their hands on and find ways to integrate what they learn about themselves.”

She also cautions leaders not to “leap into leaving” when they feel uninspired with their position. “They may need to do the self-work first before deciding to transition to another job or company,” she says. If you do find that leaving is necessary, make sure you understand what you are running to, versus running from.
PUT PEOPLE IN THE RIGHT JOBS

"Get the right people on the bus," says Liz Callahan, executive and team coach for Full Spectrum Coaching, Concord, California. She explains this means ensuring you have the right people in the right roles, and that you have the highest level of trust and confidence in their ability to execute their jobs.

Many C-suite execs spend too many hours doing things that aren’t part of their job, she says. A lot of this is related to over-site—checking in, monitoring, second guessing, reviewing what someone has done, and while important, she notes this is not what executives were hired for and could lead to burnout.

“Get the right people that you are confident in so there’s a need for constant oversee and second guessing,” Callahan says. “When you can do that, you can stop doing their jobs and start doing yours.”

IMPROVE YOUR TEAM

When looking to move up the ladder, it’s important for executives to have teams that are just as successful as they are.

“You will advance your career if you put the emphasis on advancing other people’s careers,” says Jim Vaselopoulos, founder and 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 on 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, he says.

BUILD YOUR ‘RESILIENCY’ MUSCLES

Carol Vernon, certified executive coach with Communication Matters, an executive coaching and training company in Washington, D.C., says in the high stakes world of healthcare, it’s absolutely necessary to build strong “resiliency muscles.”

“My advice is to take time to focus on building resiliency by identifying and focusing your energy on those things that you have control or influence over, rather than things or situations out of your control, and accept circumstances that cannot be changed,” Vernon says. “Nurture your relationships and rely on others for support during times of stress and adversity, both at work and home, and protect yourself from work and personal relationships that drain you, and ultimately, reduce joy and pleasure in your life.”

Resiliency can dramatically impact your executive presence, she says. If you allow the stresses of your work to impact your health and well-being, this will lead to poor concentration and lack of focus, anxiety, impaired decision making, lack of creativity, and self-doubt.

DEVELOP YOUR SUCCESSOR

Ironically, one of the primary reasons executives are not promoted is that they are indispensable in their current position, says Ted Beasley, lead instructor for Emergent Execs, Austin, Texas. He says that’s why it’s important to develop someone “on the bench” to replace you if you are 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 and competencies,” 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.”

Leadership Attributes

“Leaders today must embrace the possibility of the impossible to envision a new and amazing healthcare system.”

—DAVID GALLEGOS, CHANGE HEALTHCARE

INTERPERSONAL SENSITIVITY

Retaining talent is always challenging, but it’s more difficult now because of continuous changes brought on by external governmental pressures, constantly shifting internal strategies, and increasingly complex roles. Research from Herrmann’s firm shows that the best way to retain highly skilled employees is through ongoing coaching and professional development. Strong talent development programs also strengthen succession planning by assessing existing talent (identifying high performers and their skills), growing people’s capabilities, and ensuring there is sufficient talent throughout the organization to step into critical roles when changes occur, Herrmann says. This lessens the organization’s vulnerability when key talent is lost.

Healthcare executives who excel at developing others’ talents are goal oriented and love to learn new skills themselves. “They are good at listening and skilled at building trust and rapport,” Herrmann says. “Because they possess interpersonal sensitivity, they have a gift for enhancing morale and loyalty.”

Retaining employees is also tied to the senior executive team upholding the organization’s core values and culture. “If leaders don’t behave in a manner that is consistent with the health plan’s stated values and culture, the entire organization suffers,” Eder says. “These leaders lose authenticity with employees, which can result in a trickle-down effect wherein employees no longer feel that they themselves need to behave consistent with core values.”

Central to leadership is building a relationship of trust with the workforce. That means leaders need to follow the four basic principles of trust: honesty, integrity, loyalty, and promise keeping, says Eder. “Trust is easy to lose and hard to regain.”
VISIONARY OUTLOOK

Data is proliferating, the popularity of wearables and tracking devices is growing, smartphones are creating continuous connectivity, and the pace of innovation is skyrocketing. "Exponential technologies—including cognitive computing via artificial intelligence and machine learning, are paving the way for remarkable changes in the delivery, treatment, and reimbursement of care," says Steve Whitehurst, CEO of Health Fidelity, a healthcare technology startup.

In the face of this rapid modernization, executives must embrace institutional change management principles, and set realistic expectations for adoption," Whitehurst says.

David Gallegos, senior vice president of consulting services at Change Healthcare, a healthcare consultancy, says the key for healthcare executives is not to focus on one disrupting technology or trend, but to keep an eye on them all. Autonomous vehicles, drones, blockchain, artificial intelligence, precision marketing, robotics, voice recognition, facial recognition, genomics, and others will all potentially have a huge impact on healthcare, but their impact will be multiplied when deployed together, he says.

"Consider this scenario: A healthcare organization may need to leverage artificial intelligence to create personalized instructions that are shared securely over a blockchain network. Those instructions may then be used to enable a robot to print a precise biosimilar pharmaceutical based on the unique genomics of a patient. That information may then be used during a virtual office visit where a patient’s and doctor’s identity have been verified by voice and facial recognition. "Leaders today must embrace the possibility of the impossible to envision a new and amazing healthcare system," Gallegos says.

Fox says executives who don’t understand what’s possible, and who don’t understand technology’s limitations, will not be able to lead effectively. “Solutions will be created that may have worked but don’t because leadership does not understand how to fully use the tools in front of them,” he says. “Building an agile organization, including incorporating technology that can react to the changing landscape, is crucial.”

"Traditional health plan leaders who don’t familiarize themselves with issues that were previously in a provider or pharma category … won’t be able to stay competitive.”

—BILL FOX, MARKLOGIC

A WIDE-RANGING INTELLECT

“The leaders who provide the greatest value are those who have an interest and understanding of the business beyond their own department and an appreciation of how the many components fit together to better serve the plan’s customers and provider partners,” Eder says. “I have observed executives with strong financial expertise successfully take on the challenges of network development and contracting, as well as an internal general counsel who became a successful operational leader.”

Regardless of one’s specific area of expertise, when senior leaders are sitting around the table it is expected today that each person knows a little about finance, law, marketing, employee relations, and information technology, and can recommend ideas on how to improve the member experience and enhance success, Eder says.

Along these lines, Fox says leaders also need to effectively manage the transition from traditional healthcare business models (i.e., insurer, provider, pharmacy) to new business models that require understanding the entire ecosystem. "Consolidation, mergers, and acquisitions are moving healthcare toward a patient-centered consumer world," he says. "Traditional health plan leaders who don’t familiarize themselves with issues that were previously in a provider or pharma category, such as real-world evidence or pharmacy benefit management, won’t be able to stay competitive.”

Given the interconnections that now characterize the industry, healthcare leaders must carefully balance clinical and managed care perspectives, says Hermann. “These new hybrid roles benefit from a combination of skills including a focused learning approach and the ability to effectively listen and consider others’ opinions," she says. "These executives are achievement oriented and able to execute quickly and accurately. They are diligent enough to grasp important details while able to astutely and efficiently assess different options. These leaders provide structure for their teams and can translate theoretical concepts into corporate initiatives.”
You know something called H.R. 1628 Section 12 might change everything.

No one knows your business better than you. And with how quickly healthcare changes, you also know that you have to evolve with it. MB’s expanded healthcare team is here to offer your business creative ideas on how to stay on top of changing healthcare regulations and technology to better help the people you care for.

MB Financial Bank
Boost Member Satisfaction

Ten tactics plans should consider by MARK ROWH

Tip #1
Rethink your call center
"In era of healthcare consumerism, more health plan meme expecting a level of sophistication and customization that most 'analog' contact centers cannot meet. Technology and services that address unified customer engagement operations and seamless digital self-service, complemented by trained customer engagement specialists, can better align a contact center with the mission and vision of the entire organization. You will have to refocus your call center to reflect your brand promise and truly enable an effortless experience."
—Anand Natampalli, senior vice president, global business development for HGS, a provider of business process management services.

Tip #2
Embrace consumerism
"Payers can do this by providing more clear pricing transparency through publishing accurate prices for cash-pay individuals and participating in emerging on-demand health platforms. They should have readily accessible platforms that translate complex pricing language into terms that customers can understand."
—Bill Shea, vice president of Cognizant, a professional services company.

Tip #3
Clarify and simplify
"Make sure your plans are easy to access, understand, and compare digitally. If your plans aren’t clear, then consider partnering with an innovative expert to help you translate and differentiate your offerings. Until recently, nobody but HR, benefit managers, and brokers really understood health insurance. Today, plan members are more active than ever in deciding and paying for their plans, and they only want to use the easiest platforms available."
—Mike Levin, CEO of Vericred, a healthcare data services company.

Tip #4
Focus on cost management
"When considering keeping patients happy and retention high, cost is a huge talking point. Patients get frustrated with multiple, conflicting, or higher-than-expected charges. Because getting a fair price and smooth service are key for consumers, health plan members are happier when costs are fair and charges are accurate, which can all be vastly improved by including a payment integrity service in your cost management program."
—Chris Dorn, SVP of payment integrity services at MultiPlan, a healthcare payment firm.

Tip #5
Get personal
"We connect with members in a variety of ways to offer personal support with every aspect of their health. Leveraging advanced analytics, we recommended actions to proactively address health needs and help individuals reach their health goals. For example, an expecting mom may access a prenatal application, connect with a care coordinator, participate in a nutrition program, and join an online parenting community."
—Susan Lee, senior director of care and wellness for Florida Blue.

Tip #6
Use analytics
"In the health plan realm, member happiness is of utmost importance and a strong indicator of whether an individual might leave the plan. But what is the best method for accurately measuring member satisfaction? Health plans are increasingly tapping new source data, including social media and call center data, to enrich existing data sources and learn more about the voice of their members. Applying analytics to such data, health plans can more effectively gauge and predict member satisfaction. Which among them are most likely to file a complaint? Which are apt to leave the plan? Which have a high customer lifetime value or net promoter scores? Armed with this detail, health plans can tailor programs and services to better serve their members, increasing both satisfaction and retention in the process."
—Amanda Barefoot, principal healthcare consultant at SAS, a software company.
Tip #7
Promote goal achievement
“Retaining members is all about helping them meet their individual health goals—whether that’s managing their insulin levels, being well enough to walk their daughter down the aisle, or run a marathon. We help them achieve their goals through multidisciplinary integrated care teams and a network of community resources that brings the care tools they need to their doorstep. Health plans must act as advocates for the consumer along their personal health journeys. Acting to connect and coordinate members with local providers, resources, and services to improve their quality of life is key.”
—Dan Finke, senior vice president of Aetna’s products and services division.

Tip #8
Meet provider needs
“Risk-based contracts move the needle on health and cost outcomes if providers are given the data and tools they need to earn their incentives. And providers are increasingly savvy about this. Let them know right away during contract negotiations what information and infrastructure they will be given to improve the health of all patient populations and to meet their quality measures.”
—Scott McFarland, president of HealthBI, a provider of population health management technology and services.

Tip #9
Simplify payments
“Payers have the opportunity to make a significant impact on the consumer experience. Payer organizations have invested heavily in member portals and apps; however, these tools often lack useful and robust healthcare payment information and options. Payers can retain members by helping them navigate healthcare payments, from understanding terminology such as deductible, copay, and coinsurance, to allowing members to pay all of their providers using a digital wallet. By doing this, payers also make it easier for providers to connect with their patients and streamline their payment processes as well.”
—Deirdre Ruttle, VP of strategy at InstaMed, a healthcare payments network.

Tip #10
Understand member needs
“Members need to be cared for and understood to be happy with the plan and stay with the plan. This is easier said than done since each member’s definition of ‘cared for’ and ‘understood’ is different depending on their needs, culture, and clinical/psychosocial profile. Our view is that to keep members happy, healthy, and in control of their health, we need to understand each member’s greatest health challenge and try to work with the member to solve this challenge.”
—Saeed Aminzadeh, CEO of Decision Point Solutions, a management and technology company.

Two plans with highest customer satisfaction
Kaiser Permanente is the highest ranked plan nationally when it comes to Medicare Advantage member satisfaction. That’s according to the J.D. Power 2018 Medicare Advantage Study. The annual study, based on a survey of Medicare Advantage members, provides competitive benchmarks for the largest Medicare Advantage plans nationally. Kaiser also receives the highest score for being customer-driven. Specific actions that drive higher satisfaction conducted by the plan include:

- Excelling at helping members keep out-of-pocket expenses as low as possible, with 63% of respondents indicating Kaiser has done so.

Highmark is ranked second in terms of member satisfaction. Members perceive the plan to have a good reputation overall:

- 100% of members feel their doctors treat them as a partner in their medical care.
- 91% say all the doctors they want to see are included in network.
- 98% say their most recent question or problem was resolved.
Last year, generic drugs generated $265 billion in savings in the United States, with $6.06 as the average patient copay for a generic prescription. “The Generic Access and Savings Report in the United States 2018,” released by the Association for Accessible Medicines (AAM), found that 90% of generic prescriptions are filled at $20 or less and that generics account for nine out of every 10 prescriptions filled in 2017.

“It’s absolutely spot on,” says Robert Frankil, RPh, president and owner of Sellersville Pharmacy, Inc., in Sellersville, Pennsylvania. “Generics, for the most part, 19 out of 20 times, are going to deliver a quality product and savings to the consumer and the insurance company.”

Other findings from the report include:

- Savings for Medicare amounted to $82.7 billion, or $1,952 per enrollee.
- Savings for Medicaid was $40.6 billion, or $568 per enrollee.
- Medicines used by older adults (ages 40 to 64 years old) and seniors accounted for 80% of the $265 billion savings generated.
- The average state saved $5.2 billion in 2017, ranging from $354 million in Alaska to $23.4 billion in California.
- Brand name drugs represent only 10% of prescriptions, but 77% of drug spending.

The top 10 generic drugs ranked by savings are: atorvastatin (Lipitor); ondansetron (Zofran); omeprazole (Prilosec); gabapentin (Neurontin); simvastatin (Zocor); rosuvastatin (Crestor); amlopidine (Norvasc); aripiprazole (Abilify); montelukast (Singulair); and quetiapine (Seroquel).

For the first time, the study breaks down total savings by patient condition. Patients with mental illness saved the most through generics—$48.4 billion—followed by patients with heart conditions ($47.6 billion); epilepsy ($17.3 billion); cancer ($10.1 billion); and diabetes ($7.8 billion). The tenth edition of the AAM report was produced by the IQVIA Institute for Human Data Science.

**PRICE DEFLATION**

Craig Burton, AAM vice president of policy, says there were no surprises about the impact of generics. “It really reiterates the value proposition. It is putting
numbers to what people intuitively know about the value of generics," he told Drug Topics.

While not a surprise due to the consolidation in the buying consortia, which has three main companies controlling 90% of the market, Burton says the report clearly showed price deflation.

"On the one hand, you have significant market penetration with 90% of all prescriptions filled by generics. Patients are benefitting. Payers are benefitting. Yet at the same time you have a historically high rate of price deflation on generics," Burton says. "We've always had that. It's the nature of the generic industry. But the trends we see over the last two years have been almost two years of solid, sustained, and steep price deflation."

Frankil agrees, noting, "It used to be generics across the board were more profitable for pharmacies to dispense and that is being squashed down quite a bit. Sometimes I can actually make more money selling a brand drug."

"I never would have dreamed 10 years ago that we'd be getting so much downward pressure on generics," he adds.

In addition to market imbalance, the report, which also examines the biosimilars market, describes what it calls "anticompetitive abuses."

"Some brand manufacturers are gaming regulations to attain unwarranted extensions of the market monopolies by keeping generic and biosimilar competitors from developing and introducing lower-cost medicines," the report states.

It also calls out federal and state lawmakers for not understanding differences between the generic and brand business models and enacting one-size-fits-all legislation and regulations that have "unintended and harmful outcomes."

Burton says barriers need to be removed so more manufacturers can get into the market, adding that is also affecting the biosimilars market.

"The FDA has been making great progress in terms of approval. Today there are 11 approved biosimilars, which is great, but only three are on the market," he says. 

Gail Kalinoski is a contributing editor to Managed Healthcare Executive's sister publication Drug Topics. This article originally appeared in Drug Topics.
A potential new law aims to address the rising prices of pharmaceutical drugs by requiring price transparency. The law, known as the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, would require drug manufacturers to notify HHS and submit a transparency and justification report 30 days before they increase the price of certain drugs by more than 10% over one year or by more than 25% over three years.

“At a minimum, it will cause drug companies to reconsider price increases by having to disclose actual costs versus revenue and justify increases.”

JODIE THELLIN SKYBERG

Manufacturers would need to provide a justification for each price increase; manufacturing, research and development costs for the qualifying drug; net profits attributable to the qualifying drug; marketing and advertising spending on the qualifying drug; and other information as deemed appropriate.

Although the act would not prohibit manufacturers from increasing prices, it would give consumers notice of price increases and bring basic transparency to the market for prescription drugs for the first time.

On July 30, Rep. Francis Rooney (R-FL) became a cosponsor of a bill supporting the FAIR Drug Pricing Act, making it bipartisan in both the House and Senate—and consequently increasing its momentum. The bill still needs to be considered by committees in both the House and the Senate before coming to a full vote in both chambers.

Industry experts have varying opinions on how the act could affect drug prices.

Under the act, companies would need to file paperwork with HHS, which would then be posted for public viewing. “None of this limits price increases, it only requires more public disclosure of increases,” says Stacie Dusetzina, PhD, associate professor of health policy, Vanderbilt University School of Medicine, Nashville, Tennessee.

“Yet companies may rethink increasing prices if filing these reports is time consuming or would create significant public backlash.”

Along these lines, Jodie Thellin Skyberg, global pharmacy and pharmacy benefit manager practice leader at Cognizant, a technology and consulting services company, says the new legislation might discourage companies from raising prices dramatically, given the exposure and the negative impact to a company’s brand. “At a minimum, it will cause drug companies to reconsider price increases by having to disclose actual costs versus revenue and justify increases,” she says.

Yana Paulson, PharmD, chief pharmacy officer, LA Care Health Plan, a health insurer in Los Angeles, says public pressure, greater scrutiny, and laws like this one will likely help to keep drug price increases down. “This is because over the last two years, when the press and lawmakers have paid a lot of attention to the issue, drug price increases have slowed,” she says.

While the act may initially cause pharmaceutical companies to think more about price increases, Sharon K. Jhawar, PharmD, MBA, BC-GP, chief pharmacy officer, SCAN Health Plan, a health insurer in Long Beach, California, however, believes drug companies will find ways to work around the system. She says she wouldn’t be surprised to see companies limiting increases to 9.9% of the wholesale acquisition cost to avoid needing to notify HHS or applying different interpretations of the one- and three-year periods, as the bill is somewhat vague and provides a way to avoid notifying HHS of price increases above 10% and 25%, Jhawar says.

“It may have an unintended consequence of manufacturers setting even higher list prices when a medication first launches on the market, since increases thereafter above 10% in a 12-month period would require a notification.”

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Staying relevant
“Healthcare will always remain a viable industry,” says Ruchin Kansal, leader of health IT company Virtusa’s digital business strategy group. “However, given the unsustainable economic burden of healthcare and resulting pressure to disrupt the incumbent healthcare business model, the questions healthcare execs are asking are: How can their business remain relevant? How do they defend the potential for disruption? And how do they drive growth?”

Providers as payers
“Leading practices are transforming to integrate multiple sources of patient data, risk stratify their populations, prioritize interventions including launching new care management and navigation capabilities, and achieve decreases in avoidable cost drivers such as inpatient stays and ER visits while revisiting appropriate end-of-life care,” says Charles Saunders, MD, CEO at healthcare IT company Integra Connect. “Skills, tools, and workflows that were once the exclusive domain of payers are now high among practices’ priorities.”

Amazon’s foray into healthcare
Amazon’s decision to buy PillPack and to join forces with Berkshire Hathaway and JPMorgan Chase & Co., has healthcare executives standing at attention. “Amazon’s singular focus on improving the customer experience in every business make them a welcome, vaunted entrant into the healthcare value stream,” says Sriniv Koushik, chief technology officer of managed care company Magellan Health. “This should cause all of us to really think about how we leverage our experience in the industry to deliver real value to our customers/members by helping them live healthy and vibrant lives.”

New market entrants
Examples include UnitedHealthcare’s Optum unit buying healthcare providers and the Cigna-Express Scripts deal. “Surprisingly many organizations still seem to believe that the disruption will impact others more than it will impact them,” says Liam Walsh, line of business leader for Healthcare & Life Sciences at KPMG, a tax, audit, and advisory firm.

End-of-life programs
Saunders points to the April announcement that Humana and two private equity firms are acquiring privately held hospice operator Curo Health Services. “The Humana acquisition news underlined an issue that was already top-of-mind for many specialists participating in value-based programs: the importance of incorporating appropriate, compassionate end-of-life care for patients,” he says. “Our data show that even some of the largest oncology practices, for example, introduce end-of-life discussions too little and too late. While the practices are seeking to improve the situation with increased education and enhanced programs, part of the answer will also lie in the continued progress of precision care.”

Value-based care and patient-centricity
While these issues are on everyone’s mind, executives must not overlook the interdependence of these topics, says Jennifer Bright, acting executive director, the Innovation and Value Initiative, a collaboration of academics, patient advocacy organizations, payers, and life sciences companies. "Executives can benefit from models that integrate multiple measurement tools with the patient perspective at the forefront, so they can move beyond short-term price focus to assess real-world value,” Bright says.

In case you missed it
Help your organization innovate, see PAGE 43
Encouraging patients to follow up with their primary care doctors within one week of discharge is key to Tandigm Health’s strategy of reducing readmissions. The Conshohocken, Pennsylvania-based population health organization discovered that high-risk patients who followed up with their primary care physician (PCP) within seven days had a 10%, 30-day readmission rate. Those who didn’t see their PCP in that same timeframe had a 17% readmission rate, despite both groups having nearly identical LACE index scores. The LACE index identifies patients who are at risk for readmission or death within 30 days of discharge.

“Our value-based program is designed to engage doctors by providing meaningful incentives that ultimately reward them for improvements in the quality and cost of healthcare,” says Ken Goldblum, MD, chief medical officer, Tandigm Health. “As our data began to show the benefits of following up with a PCP post-discharge, we added a metric to our incentive plan and started to reward physicians for following up with their patients within seven days of a hospitalization.”

With that incentive in place, the hospital’s follow-up rate increased from 25% to 54% in just one year.

It’s critical for patients—and their care teams—to have a clear understanding of their needs and expectations following a hospitalization, says Goldblum. When care isn’t coordinated, important parts of a patient’s journey to improved health can fall through the cracks.

“Prompt PCP follow-up post-discharge is an important way to bring all the parts of the care process together, allowing PCPs to connect the dots and identify any potential issues that may have been otherwise overlooked,” he says. “It’s also important that a patient knows who to turn to when a problem arises.” That’s why Tandigm Health has a team of telephonic nurses that follows up with high-risk patients quickly and regularly after they are discharged from a hospital or nursing facility to educate and assist them with their transition of care.

There are several other strategies healthcare organizations can employ to reduce readmissions. Here are seven more.

**FOCUS ON HEALTH LITERACY**

Discharge paperwork can sometimes be tricky to understand, especially for someone who has just undergone a health scare and wants to return home as quickly as possible. Joseph Geskey, DO, vice president of medical affairs, OhioHealth Doctors Hospital in Columbus, Ohio, says this is why the hospital prioritizes ensuring patients under-
stand their discharge instructions.

"For example, every patient should benefit from having discharge instructions that are written at a fifth-grade reading level," he says. "Hospital staff should ensure that patients can ‘teach back’ the instructions they have been given. This helps us to see that patients have understood them."

Additionally, patients should know what problems to look for when they leave the hospital, what they should do if they encounter them, and who they should call if they have questions, says Geskey. Care coordination is critical in that the right care at the right time allows optimal stewardship of resources to be deployed to the individuals who need them most. This improves efficiency, equity, and effectiveness, he says.

The program has led to a 40% reduction in readmissions for those patients involved in the pilot.

"With our Healthy Literacy pilot program, we screen patients for health literacy and how engaged they are in their care," he says. "If they have limited health literacy, meet Medicare homebound criteria, and decide to use OhioHealth Home Health, myself and two other OhioHealth Home Health nurses visit their homes for one hour per week for four weeks."

There, they work on everything from understanding medications to knowing what foods they should be eating based on their diagnosis. The program has led to a 40% reduction in readmissions for patients involved, and has increased patient engagement, says Geskey.

"We will never be able to reduce the cost of healthcare unless we can get patients to partner with us more effectively," he says. "This builds relationships such that instead of looking at people as being noncompliant, or unwilling to help themselves, we are motivated in helping them creatively solve problems that allow them to be a person who has an illness like congestive heart failure, rather than a congestive heart failure patient."

Geskey believes patient education is the one aspect of healthcare that has been systematically underutilized. "Instead, at times, we deploy technological solutions instead of personal connections that employ clear communication, an understanding of the patient, and the struggles he/she labors under," he says. This makes it difficult to build trust.

Over the course of the Healthy Literacy pilot program, Geskey has visited more than 100 homes. He says effective education meets patients where they are, assesses how patients best learn information, assesses whether they understand the information, and helps patients set goals and breaks down barriers in attaining those goals.

2 Use a prediction tool
Michael Gentry, senior vice president and COO of Sentara Healthcare, the company that oversees Sentara provider divisions, including 12 hospitals, Sentara Life Care Corporation, and Sentara Enterprises, suggests utilizing HOSPITAL SCORE.

This tool identifies patients at the highest risk of avoidable readmissions before they are discharged, and it has helped tremendously with risk stratification, says Gentry. It predicts 30-day readmissions based on the following predictors at discharge:

- Hemoglobin level
- Discharge from an Oncology service
- Sodium level
- Procedure during hospital stay
- Index admission Type
- Number of Admissions during the previous year
- Length of stay

The higher the HOSPITAL SCORE (0-11), the higher the risk of a 30-day readmission. Risk categories are considered Low (0-4), Intermediate (5-6), and High (7+).

"This process is only a year old for Sentara so there is not much data yet; however, our initial study shows strong correlation between a high HOSPITAL SCORE and readmission rates," Gentry says.

Other ways Sentara has reduced readmissions include documenting the patient’s...
An effective approach:

- Assesses how the patient best learns.
- Assesses whether the patient understands the information.
- Helps the patient break down barriers in attaining goals.

**3 EXTEND YOUR REACH**

Denise Buonocore, MSN, RN, incoming chair of the AACN Certification Corporation, the credentialing arm of the American Association of Critical-Care Nurses, serves as acute care nurse practitioner for heart failure services at St. Vincent’s Medical Center in Bridgeport, Connecticut. Part of her responsibility is taking charge of the readmission effort for heart failure services.

“When I first started the initiative, I realized that at least half of what affected readmissions happened outside the hospital. In order to be effective, we needed to disrupt and transform the whole care continuum,” she says. “Knowing our patient demographics and population, we knew we had to create interventions that would minimize disparity in care and create the right transition for every patient every time.”

Part of her strategy is getting all parts of the care continuum inside and outside of the organization, including patients and families, working toward the same goal.

“When we started our readmission journey, we engaged key leaders and staff inside the hospital and out in the community, including home care agencies, skilled nursing facilities, hospice agencies, medical practices, and patients, to help us understand the challenges,” she says. “We then created systems, processes, and expectations to overcome the challenges that patients and families face. This eventually evolved into a clinically integrated network.”

While she agrees that patient education is important, she says teaching patients to be empowered as full participants in their care and decisions is equally important. For example, she says you can teach patients the signs and symptoms of worsening disease and explain what to do. But unless you are using teach back to ensure they understood and have a well-thought-out plan for what to do next, who to call, and when to call, they will probably end up back in the hospital.

**4 USE OUTSIDE RESOURCES**

Laura Adams, president & CEO of Rhode Island Quality Institute, Providence, Rhode Island, notes the organization has found great success in helping hospitals limit readmissions through the use of its Care Management Alerts and Dashboards (CMADs).

The Quality Institute aggregates clinical data from across the state within a central repository known as CurrentCare, Rhode Island’s statewide health information exchange, which is powered by InterSystems HealthShare platform, she says. This information exchange includes data from several settings, including hospitals, labs, pharmacies, primary and specialty care practices, alcohol and substance use treatment facilities, federally qualified health centers, community mental health centers, and long-term care.

The CMADs draw on this data to inform providers in real-time whenever their patients are admitted or discharged from acute care hospitals, EDs, or long-term care facilities in Rhode Island. The CMADs also provide aggregate risk scores, historical admission trends, drilled down clinical data, and updated demographics.

“With the right information served up at the right time, care managers and physicians engage immediately in coordination of care,” Adams says. “Recent analysis demonstrated a reduction in hospital readmissions by 18.9% during 2017. A reduction of 18.4% was also demonstrated for patients who visit an ED within 30 days of an inpatient discharge, with a 16.1% reduction in ED return visits.”

**5 GET ALL HANDS ON DECK**

While Tandigm Health has reduced readmissions by ensuring prompt follow up with primary care physicians, it is also enlisting other healthcare team members to help in the readmission reduction battle.

“Pharmacists check patients’ medication lists to find duplicates, identify potential
negative interactions, evaluate high-risk medications, confirm dosages, and more,” Goldblum says. “Tandigm also has a team of social workers who connect with our high-risk patients, if needed, to connect them with community resources that may address social issues that may be impacting their health at home.”

Tandigm also deploys a doctor or nurse practitioner directly to the home of high-risk patients to address health needs. “We leverage a home-grown risk stratification process to help us identify these high-risk patients who need frequent, quality care or are at risk for certain conditions,” Goldblum says. “Our risk stratification process uses physician reports, admissions data, claims data, and more to examine a range of clinical characteristics of patients in our network such as utilization, comorbidities, and hospitalizations. This data, coupled with expansive physician input, enables us to assign each patient a risk score that will influence their care process.”

**ADDRESS ALL THE PATIENTS’ NEEDS**

Care coordination and communication between providers keeps a readmission prevention plan together, says Buonocore. “We utilize [registered nurse] and [nurse practitioner] navigators to help with the care coordination,” she says. “We use interprofessional daily rounds to discuss readiness for discharge, focusing on whether the condition they came to the hospital for has been adequately treated and if their comorbidities are well-addressed.”

The nurses also identify social, spiritual, and palliative issues, and collectively come up with solutions.

“Care coordination is a key factor in assuring that all the right things are in place with each care transition,” says Buonocore. “You have to remember patients and families come to us with very complex problems—not only medical problems but also psychological and social issues. If you are not addressing the whole picture, you are more likely to end up with a readmission.”

As one patient told Buonocore, “I can’t even begin to think about medications, my first priority right now is getting a roof over my head.”

“It takes a village to accomplish this work. Keep patients at the center of it,” says Buono-

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**“I realized that at least half of what affected readmissions happened outside the hospital. In order to be effective, we needed to disrupt and transform the whole care continuum.”**

DENISE BUONOCORE, ST. VINCENT’S MEDICAL CENTER

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**Check your codes**

Sentara Healthcare has improved its readmissions rate by focusing on coding accuracy. It found that some planned readmissions for patients who had follow up procedures scheduled within 30 days had incorrect discharge disposition codes, so these patient visits were characterized as *avoidable* readmissions.

“This was common in cardiac procedures where a planned follow-up procedure was needed to place a stent;” Gentry says. “Another example is oncology patients who have multiple planned procedures in a short span of time.”

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Denise Buonocore, St. Vincent’s Medical Center

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

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**Saeed Aminzadeh, CEO of Boston-based Decision Point Healthcare Solutions, believes the secret to reducing readmissions is to identify and engage patients as early as possible (ideally, before they even have their index admission).**

“Multiple, clustered admissions are a function of both clinical and engagement risk,” he says. “Members who are at high risk for multiple, clustered admissions typically have an undesirable disease trajectory as well as a history of engagement challenges, such as poor preventive behavior, sporadic visits to their doctor, excessive use of the ER, challenges with medication adherence, PCP switching, etc.”

When probed, or when data on social determinants of health is available, it becomes clear that these members often have other socioeconomic barriers, such as limited home care support, undesirable nutrition, and poor health literacy, which further compound and elevate their risk, says Aminzadeh.

“We have found that identifying and engaging these members prior to inpatient activity is key to creating sustained improvements in readmission rates,” he says. “From our work with health plans, a proactive approach is really able to move the needle and has resulted in 25% reductions in readmission rates annually.”

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**“I realized that at least half of what affected readmissions happened outside the hospital. In order to be effective, we needed to disrupt and transform the whole care continuum.”**

DENISE BUONOCORE, ST. VINCENT’S MEDICAL CENTER

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Money Matters

PRACTICAL MATTERS FOR A NEW HEALTH ECONOMY

Pharma Forecast

Important considerations in the quest to manage costs by TRACEY WALKER

The cost of pharmaceuticals continues to account for a large share of every healthcare organization’s budget and this trend is unlikely to change, according to a new drug forecast.

Health systems can expect a 4.92% increase in the price of pharmaceuticals in 2019, according to Vizient’s Drug Price Forecast. This estimate represents an anticipated slower rate of growth compared to previous Vizient forecasts, such as the 7.61% value projected for 2018.

“This growth still represents a substantial impact to member budgets,” says Steven Lucio, PharmD, PhD, associate vice president, pharmacy service for Vizient. “As a result, a continued dedication of energy and resources to ensuring optimal medication use and prescribing practices is still required by pharmacists and physicians.”

The more recent expansion of specialty pharmaceuticals is forcing healthcare institutions to change their investment approach to expand non-acute-care directed pharmacy services and view their costs and reimbursements in totally different ways, says Lucio.

“Healthcare executives must also maintain a focus on changes in the way in which new medications are developed, marketed, and delivered,” he says. “Further, they must also be cognizant of competition—in the form of generic drugs and biosimilars—as soon as they become available. Finally, they must be aware of the regulatory and advocacy-related issues that will affect practice in the future.”

Brand, specialty prices

The prices of branded and specialty drugs continue to increase and this trend is expected to persist, Lucio says. “Costs for previously approved medications, particularly those used in the oncology and immunology areas, continue to grow. More drugs are slated for approval in these clinical areas and each new drug tends to enter the market at a higher price. Many of the drugs that have consumed costs in these areas are biologic drugs that until recently—with the advent of biosimilars—were not subject to competition. While in existence, the biosimilar market is still in its formative stage and has not yet had a significant impact on pricing behaviors. The costs of therapies are expected to increase as even more personalized medications, including additional gene therapies, receive approval.”

Health executives must understand when and where these developments will take place and ensure they have pharmacist resources deployed to help physicians identify therapies that will deliver the best outcomes, says Lucio.

“While in existence, the biosimilar market is still in its formative stage and has not yet had a significant impact on pricing behaviors.”

STEVEN LUCIO, VIZIENT

Areas of greatest expense include:

- Oncology
- Rheumatoid arthritis
- Gastroenterology conditions
- Multiple sclerosis
- Other specialized disease states

“Health systems must demonstrate increased proficiency at providing high-quality care in these patient populations,” Lucio says.

Tracey Walker is content manager for Managed Healthcare Executive.
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managed healthcare executive
The amount of data in healthcare is growing, but that’s not always translating to improved patient outcomes. Why? The location, format, and structure of data continues to be siloed, which makes it hard for physicians to use data in meaningful ways.

“A good example is social determinants of health, which might indicate issues with food insecurity or social isolation, or that a person was recently widowed,” says Simon Beaulah, senior director of healthcare for Linguamatics, a UK-based machine learning provider. If that information is not captured with other patient record information, a physician could miss it, he says.

“Social determinants of health can indicate a potential increase in patient risk, which is of particular importance in a value-based care environment.”

Here are three ways healthcare organizations can better utilize their data:

1. **Combine clinical and claims data in a meaningful way**

   Too many organizations are still relying on separate data sets to make business decisions, says Zachary Blunt, manager of product management and population health at Greenway Health, an EHR and revenue cycle management software provider. “To have a complete view of the patients, this information has to be aggregated at the patient level.”

   Many payers do not provide patient level data without a risk-based arrangement, Blunt adds. Organizations will need to consider this as they begin formulating their population health strategy. But it’s not just clinical and claims data that needs to be better integrated. “There are many slices of data that organizations will need to view,” Blunt says. “These include disease registries to get insight into the pervasive chronic conditions in your population, leakage tracking with office visits, wellness visits, and analyzing claims for care rendered outside of your organization, as well as identifying high-risk patient populations with predictive tools.”

2. **Incorporate unstructured data**

   Beaulah says 80% of EHR data is classified as unstructured, meaning it doesn’t fit into traditional EHR data fields. This unstructured data includes important information that can be valuable to patient diagnoses such as clinical notes, images, and specialist reports like radiology and pathology documents.

   Also, when physicians do have the opportunity to fill data into structured formats, they aren’t always doing so, says Beulah. “While many EHRs provide extensive predefined fields to enter structured information, there is growing evidence that indicates that the time required to fill in these fields is a major contributor to physician burnout. As a result, many of these fields are not completed, nor regularly updated.”

   Clinician notes are a good example of EHR data that isn’t utilized to the extent it should be because the information is free text, so it’s not easily viewed and/or added to data analytics platforms, says Jay Anders, MD, chief medical officer of Medicomp Systems.

   Some solutions are available. For example, Phoenix Children’s Hospital implemented Medicomp’s Quippe Clinical Documentation technology, and it has saved the hospital $1 million annually in transcription fees. The software works with existing EHRs to extract data from clinical notes and complete 86% of documentation, coding, and billing the day of the patient’s service.

   The software also is being used to track juvenile rheumatoid arthritis and its effect on patients’ joints. “The ability to have intricate data collected and recorded every time the patient is seen, and trackable to the joint, is more valuable than just patient notes,” Anders says. “Those intricate notes can in-
dicate how a disease is responding to treatment, and the patient can receive immediate care.”

Anders says more structured data is an important part of powering AI and machine learning technology that is coming quickly down the pipeline in healthcare.

“All of those systems are just as good as the data they have. The more accurate the data, the better they will operate,” Anders says of AI technology. “It’s a misnomer that doctors will be able to pick up a microphone and accurately create notes, and good data behind those notes. Good structured data that can be collected outside of speech and text have a long way to go.”

3 Launch an enterprise data warehouse (EDW)

An EDW serves as a unified patient registry, which can store clinical, claims, social, and other data from multiple sources, says Alexandra Gorman, assistant vice president of business development at Lightbeam Health Solutions, a healthcare technology company.

EDWs can be used to populate reports; calculate clinical quality measures and risk scores; and view financial data that assist in achieving quality measures, she says. “A comprehensive view is critical for organizations and payers who strive to improve clinical outcomes, reduce costs, and steward healthcare resources wisely.”

Healthcare organizations searching for EDW vendors should examine the vendor’s ability to consume and transform large amounts of data from disparate systems, custom codes, and non-standard storing locations, Gorman says.

“Having a partner that has significant experience with data ingestion will eliminate trial and error and lead to a successful population health management project from the start,” she says.

Q: How would you grade your organization’s use of big data to reduce costs and improve quality?

- A: 4%
- B: 40%
- C: 36%
- D: 15%
- E: 4%

Q: What is your organization’s biggest challenge related to big data?

- Difficulty gathering information: 6%
- Difficulty exchanging information between systems: 30%
- Difficulty turning data into actionable information: 32%
- Not having enough staff members with adequate expertise in data analytics: 32%

Source: Managed Healthcare Executive’s Managed Care Technology Survey 2018, based on responses from more than 120 executives.

Have You Considered a Center of Excellence for Data?

A Center of Excellence (COE) is a specialized department of interdisciplinary experts that focuses on a specific issue. Many hospitals have created COEs for clinical issues, such as diabetes or women’s health, and business issues. Gurjeet Singh, CEO of Ayasdi, an artificial intelligence platform, says that a COE that focuses on actionable data and artificial intelligence (AI) is also imperative.

“Staffing up—with present and future leaders—a core group that can establish governance, set priorities, document and communicate wins, and set strategy will ensure that the organization optimizes its investment,” Singh says.

One of the most notable features of a COE is the depth and breadth of qualifications possessed by their personnel, according to a 2017 BMC Health Services Research report.

“These experts are assembled via carefully-planned organizational structures into collaborative, interdisciplinary teams and directed in a manner to deliver exceptional care, something facilitated by open communication, including formal opportunities to share experiences,” according to the report.
Early 19% of U.S. adults have experienced some form of mental illness and over 4% have a serious mental illness, according to the National Institute of Mental Health (NIMH).

Medicines are one part of a personalized treatment plan for mental illness. However, according to the NIMH, it often takes time and patience to find a combination of therapies that work best for each patient.

“A great challenge in treatment is that patients often experience more than one psychological issue—for example, schizophrenia, depression, and substance abuse,” says Jennifer Seagle, PharmD, area clinical manager for CompleteRx. “It is not uncommon to see patients on multiple treatment agents, which all have the potential to interact with each other—or other medical treatments—and potentially exacerbate their comorbidities, cause excessive sedation, or have unwanted side effects.”

Current treatments
Several different classes of medications are used to treat mental illnesses and not all therapies work the same in every patient.

“The current DSM-5 (Diagnostic and Statistical Manual of Mental Disorders-5) manual does not provide treatment recommendations. Likewise, many mental health guidelines don’t recommend one class of agents over another for treatment of patients with mental health disorders, nor do they recommend a specific agent in a class, as exemplified by the APA guidelines on Major Depressive Disorder,” Seagle says. “There is also a distinct lack of data to support superior efficacy amongst antipsychotics for conditions such as schizophrenia and bipolar I disorder, apart from clozapine in treatment-resistant patients. Providers must consider side-effect profiles, patient preference, compliance issues, and cost when selecting therapy.”

One trend Seagle is seeing is increased use of newer antipsychotics such as lurasidone (Latuda) and iloperidone (Fanapt) competing with much less-costly agents that have gone generic such as risperidone (Risperdal) and quetiapine (Seroquel).

For patients where adherence or taking oral medications is an issue, there are several long-acting antipsychotic injectables available on the market, Seagle says. “These come with a hefty price tag and cost may be an issue for patients as well as the challenge prescribers would face titrating doses, as often these are weekly or monthly injections.”

Pipeline treatments
According to the PhRMA “Medicines in Development for Mental Illnesses 2017 Report,” more than 140 medicines to treat mental illness are in development.

ALKS 5461 (Alkermes), a novel once-daily oral agent for depression, combines buprenorphine and samidorphan. It is in clinical trials and under review by the FDA. Alkermes has another candidate, ALKS 3831, a novel combination (samidorphan, olanzapine) antipsychotic that is expected to reduce the metabolic adverse events and weight gain, Seagle says.

Other potential therapies listed in the PhRMA report include an intranasal drug in development for treatment-resistant depression, and a subcutaneous long-acting formulation of buprenorphine for opioid use disorder.

There is increased use of newer antipsychotics such as lurasidone (Latuda) and iloperidone (Fanapt) competing with much less-costly agents that have gone generic such as risperidone (Risperdal) and quetiapine (Seroquel).

—Iennifer Seagle, CompleteRx
Military-Specific Mental Health Program

How it meets their unique needs by TRACEY WALKER

Military service members and veterans continue to pose unique healthcare needs and increasingly prevalent behavioral health challenges.

Not your typical program

PSP programs range from well-established, evidence-based therapies leading to quality patient outcomes to groundbreaking research incorporating innovative treatments. Some of the specialty programs and treatment modalities include:

- **Emerald Coast Behavioral Hospital (Panama City, Florida):** Yoga instituted as a treatment in 2015; benefits for reducing stress in the body and mind.
- **Laurel Ridge Treatment Center (San Antonio, Texas):** Transcranial magnetic stimulation focuses electronic pulses on small areas of the brain believed to control mood and the source of symptoms for PTSD.
- **Chris Kyle Patriots Hospital (Anchorage, Alaska):** Six-week creative art therapy program with a focus on progressive music therapy as well as other art forms; recently highlighted at a White House event.
- **The Vines Hospital (Ocala, Florida):** Equine therapy supports veterans suffering from challenges including PTSD and substance abuse.

As many as one in five veterans who have served in Iraq or Afghanistan may experience symptoms of PTSD in a given year, according to the U.S. Department of Veterans Affairs. Every day in America, some 22 veterans commit suicide, just short of one per hour. And while veterans make up only 8.5% of the overall population, they account for 18% of all suicide deaths. In recent years, more active duty soldiers have died from suicide than combat operations.

Universal Health Services (UHS), which has a mental health treatment network of more than 300 behavioral health centers in the U.S., U.K., and Puerto Rico, offers mental health treatment for the general public, as well as treatment programs specific to U.S. active military and veterans.

Over the past 15 years, UHS has significantly expanded its collaborations with military leaders and behavioral health experts including the establishment of the U.S. Patriot Support Program (PSP) in 2001. PSP was born to support the care provided through the Department of Defense and Veterans Administration and to ensure consistency in practices across Patriot Support facilities.

Unique to each community

The role of the PSP is to provide a consistent set of core standards and practices across participating PSP treatment facilities. While there is a core standard of care, each program constantly evolves to meet the often-unique needs of the military or veteran community it serves, utilizing the latest evidence-based treatment modalities. UHS works closely with local installation command to customize its programs.

All UHS Patriot Support Center facilities are TRICARE certified and contract with TRICARE-designated managed care organizations. The facilities also accept Medicare, Medicaid, and most private insurance plans.

As a former military officer and founder of the largest provider of inpatient behavioral healthcare in the nation, Alan B. Miller, CEO and chairman of UHS, has a special affinity for this group of patriots. “After graduation, I was commissioned in the U.S. Army and served in the 77th Infantry Division,” says Miller. “UHS’ commitment to military members and their families, for me, is very personal. Like all of our behavioral healthcare treatment, our PSP demonstrates our commitment to total patient care—treating the mind and body of our patients and enabling them to live their best life.”

Military-specific approach

Today, 11 UHS behavioral health PSP “Centers of Excellence” and 13 Support Service Centers coordinate closely with medical and clin-
ical staff at military installations to provide dedicated, specialized treatment programs for service members, veterans, and their dependents.

In 2017, PSP facilities served some 6,500 service members and veterans utilizing evidence-based treatment models. The vast majority of PSP treatment centers are located in close proximity to installations, providing convenient access for patients, their families, and base commanders.

During the past decade, increased investment in research and education often headed by dedicated military and VA clinicians has resulted in promising advances in diagnosis and treatment, according to Miller. “Similarly, there is improved public recognition that combat stress, PTSD, depression, anxiety, and substance use disorder are genuine, serious and treatable medical conditions,” he says.

Miller encourages healthcare executives and other stakeholders to help end the damaging stigma concerning mental illness.

“A key facet of this comes in the form of highlighting the issues of PTSD and post-combat transition as part of the overall national dialogue on mental illness,” he says.

There is no one-size-fits-all treatment approach for PTSD and post-combat transition, Miller says. “Each patient is therefore provided individualized treatments to aid in their recovery and goal of living a fruitful life, whether on active duty, a civilian or family member.”

Aligning care with value initiatives
While successful implementation of outcome benchmarking in the behavioral health space has been slow or in some cases non-existent, UHS’ facilities including PSP centers represent notably positive exceptions, says Miller.

“Our approach to value is centered on a key question which is often overlooked: ‘Did the patient get better?’ To help ensure that the answer is ‘yes,’ for the past several years PSP facilities have dramatically increased investment in and utilization of a wide variety of evidence-based clinical outcome assessment, patient satisfaction, and clinical benchmarking tools linked to improved treatments, outcomes, and overall value,” he says.

For example, the Post Traumatic Stress Disorder Checklist, is a widely used measure of PTSD symptoms including those focused on specific experiences from military service and other non-service related trauma.

“We are pleased to report that the results of these and similar evidence-based assessment tools demonstrate that approximately 80% of patients receiving care at PSP facilities for PTSD symptoms experienced clinically meaningful improvement,” Miller says. “UHS and PSP facilities continue to expand and refine the use of outcome measurement to benchmark our performance and to ensure that our programs continue to provide superior level care.”

Tracey Walker is content manager for Managed Healthcare Executive

1 in 5. The estimated number of veterans who have served in Iraq or Afghanistan who may experience symptoms of PTSD in a given year.

SOURCE: U.S. DEPARTMENT OF VETERANS AFFAIRS

Military-specific approach

PSP treatment centers operate as distinct, specialized, and independent units within the larger hospital setting and the treatment programs and protocols are tailored toward the unique requirements of military life, culture, and chain of command. This often includes:

- Hiring staff with significant VA and/or military patient care experience.
- “Total Force Fitness” modalities integrating physical, mental, social, and spiritual strength.
- Mandatory training of clinical staff in military cultural sensitivity and practices.
- Custom military themed facility designs and fixtures (e.g., flagpoles and branch flags).
- Integrating graduation and/or military style “coin” ceremonies at the conclusion of treatment.

1 in 5. The estimated number of veterans who have served in Iraq or Afghanistan who may experience symptoms of PTSD in a given year.

SOURCE: U.S. DEPARTMENT OF VETERANS AFFAIRS
Our workspaces have a substantial pull over us. They can enhance and cultivate our creativity, and in a time when businesses are continually being called on to innovate, that’s important.

If you work at a cool startup or Google, you may already work in a spaceship-inspired pod or take calls from a hammock while having your lunchtime smoothie delivered by a dog on a skateboard. But for most of us in healthcare, this isn’t our daily work life. Short of a full redesign, what can you do to pump up the creative volume in your space? Should you run out and buy a ping-pong table? Not quite. Building an innovative culture is not as simple as setting up a foosball table and turning to your suit-clad workers declaring, “We’re so zany now!” But there are some simple things you can do to encourage creativity in a genuine way.

1. Let there be light. Lighting makes a huge difference in a space. For creativity, natural light is ideal—do your best to avoid interior conference rooms with no windows. If you are stuck in a fluorescent palace, consider additional lighting. I’ve added lamps to illuminate dark corners and complement the fluorescents, so I don’t feel like I’m lying on a medical gurney while I’m trying to work.

2. Stock up on supplies. Scatter brightly colored Post-it notes and sharpies around your space. These are the tools of the innovation trade. Sketching was the first way of storytelling, and it still holds true when you want to communicate an idea. Consider covering an entire wall with dry erase paint. Flip charts and scented Mr. Sketch markers are another great method for getting things down. Having the right tools encourages us to break away from formal PowerPoints and ideate on the spot.

3. Have food for thought—literally and figuratively. Have snacks on hand because nobody can think on an empty stomach. You don’t need a fully-stocked kitchen; a bowl of snack bars can do the trick. Also consider scattering magazines or writing down links to compelling Ted talks. These can help provide inspiration and a needed break from the daily grind.

4. Pump in cool jams. Low background music sets the tone and instantly makes the environment feel more laid back. When I teach, I play music as students enter my class and when they’re doing group work. It immediately signals a vibe and tone. With Pandora and Spotify, it’s easier than ever to pick up a low-cost Bluetooth speaker and provide a soundtrack for creativity to flow.

5. Consider adding accents. If you want to really go above and beyond, consider springing for some basic home décor items. Command strips will let you hang pictures on the wall without damaging them. Throw rugs and pillows are my favorite way to make a space warmer and more inviting. Everyone comments on the gorgeous macramé pillow in my office that I found on clearance for $5!

Pulling all of this together is a small effort but makes for a big impact to daily work life. It’s a great way to delight team members using the space you’ve got. No ping-pong balls required.

Michelle Histand is an innovation director at Independence Blue Cross where she has fostered and advanced the organization’s design thinking approach to problem solving.
Lymphoma Treatment Improves
A conversation with John Lister, MD

Managing the cost of lymphoma therapy must be a priority for health executives, says John Lister, MD, professor and system director, Division of Hematology and Cellular Therapy/Transplantation, at Allegheny Health Network Cancer Institute, in Pittsburgh. “Beyond cost, a rational approach to the implementation of new therapeutic strategy is required to bring exceptional value to the patient.”

Here, Lister reveals to Managed Healthcare Executive (MHE) the status of pipeline lymphoma treatments.

Q. MHE: What new treatments should execs watch?
Lister: The recent approval of CAR T-cell therapy for the treatment of relapsed diffuse large B-cell lymphoma has significantly altered the treatment paradigm. CAR T-cell therapy represents a significant therapeutic advance that has only begun to impact the lives of patients. This treatment is extraordinarily expensive and thus will have a major impact upon the cost of treating patients with lymphoma. This might be partially offset by replacing bone marrow transplantation with CAR T-cell therapy. The application of CAR T-cell therapy to treatment of solid cancers is being tested in the laboratory and the clinic. Promising clinical data has emerged from treatment of ovarian cancer. Lessons learned from the treatment of lymphoma with CAR T-cell therapy will be of value to the healthcare executive in planning for future indications.

The introduction of biosimilar medications to compete with patent-protected medications such as rituximab might lower the cost of treating patients with B-cell lymphoma.

The recent introduction of targeted oral therapy with drugs such as lenalidomide, ibrutinib, acalabrutinib, idelalisib, copanlisib, among many others introduces new challenges for the creation of appropriate affordable coverage for the patient with lymphoma.

Highly Precise Treatment
The use of CAR T-cell therapy is bringing new levels of precision in cancer treatment. Because CAR T-cell therapies direct the potential of T-cell therapy toward specific targets, they allow for higher precision in treatments without the toxicity usually seen in common cancer treatments, says Julie Kaylor, MS, certified genetic counselor, client liaison on the genetic analyst team at InformedDNA in Maumelle, Arkansas.

She adds that these therapies represent a paradigm shift in cancer treatments, pointing out that the FDA recently approved two different autologous CAR T-cell therapies, and the American Society of Clinical Oncology named CAR T-cell therapy the “Advance of the Year” in 2018.
MORE DIVERSITY NEEDED

More than 80% of cancer clinical trial participants are white and 59% are male, according to a 2013 study published in Cancer.

“In this era of precision oncology and targeted therapies and needing to treat specific targets with immunotherapy, it’s even more important that we identify and include different populations when doing clinical trials.”

—Aditi Shastri, MD, an oncologist at Montefiore Medical Center

Quotable

“We will never be able to reduce the cost of healthcare unless we can get patients to partner with us more effectively. This builds relationships such that instead of looking at people as being noncompliant, or unwilling to help themselves, we are motivated in helping them creatively solve problems that allow them to be a person who has an illness like congestive heart failure rather than a congestive heart failure patient.”

—Joseph Geskey, DO, OhioHealth Doctors Hospital in Columbus, Ohio, pg. 32

Maternal Matters

Each year, more than 50,000 women are severely injured while giving birth. About 700 mothers die. The best estimates say that half of these deaths could be prevented and half the injuries reduced or eliminated with better care.

—“Deadly Deliveries,” USA Today

Shocking Cancer Stats

Liver cancer deaths have surged by 43% since 2000. During this time, liver cancer rose from the ninth leading cause of cancer death in 2000 to the sixth leading cause of death by 2016.

—CDC