WHICH WAY TO THE NEW NORMAL?
Searching for a Path Forward

PLUS
- Drugs in the pipeline
  SGLT2 inhibitors and GLP-1 agonists
- Pharmacy/Formulary Development
  Electronic prior authorization
- Population health
  Camden Coalition’s ‘hot spotting’ adjustments

August 2020 VOL. 30 NO. 8
Managed Healthcare Executive.com
FDA approved for several indications, including Diabetic Retinopathy (DR)

With demonstrated outcomes for members backed by extensive clinical experience, EYLEA delivers

PROOF RIGHT BEFORE YOUR EYES

EYLEA® (aflibercept) Injection
For Intravitreal Injection

IMPORTANT SAFETY INFORMATION AND INDICATIONS

CONTRAINDICATIONS

- EYLEA is contraindicated in patients with ocular or periorcular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.

- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

REGENERON

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777 Old Saw Mill River Road, Tarrytown, NY 10591
*Wet Age-related Macular Degeneration (AMD): The recommended dose of EYLEA is 2 mg administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every-4-week (monthly) dosing after the first 12 weeks (3 months). Although not as effective as the recommended every-8-week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly. Diabetic Macular Edema (DME) and DR: The recommended dose of EYLEA is 2 mg administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every-4-week (monthly) dosing after the first 20 weeks (5 months).

ADVERSE REACTIONS
- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

INDICATIONS
EYLEA® (afiblercept) Injection 2 mg (0.05 mL) is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

Please see Brief Summary of Prescribing Information on the following page.

Table 1: Most Common Adverse Reactions (≥5%) in Wet AMD Studies

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Baseline to Week 52</th>
<th>Baseline to Week 96</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EYLEA (N=142)</td>
<td>Control (N=92)</td>
</tr>
<tr>
<td></td>
<td>(N=287)</td>
<td>(N=287)</td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
<td>23%</td>
<td>19%</td>
</tr>
<tr>
<td>Diplopia</td>
<td>9%</td>
<td>10%</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>6%</td>
<td>2%</td>
</tr>
<tr>
<td>Retinal detachment</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Subconjunctival hemorrhage</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Retinal edema</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Foreign body sensation in eyes</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Ocular pain</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>Retina detachment</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Conjunctival reaction</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Conjonctival hyperemia</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Foreign body reaction</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Subconjunctival hemorrhage</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Intraocular inflammation</td>
<td>1%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Table 2: Most Common Adverse Reactions (≥1%) in RVO Studies

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Control (N=287)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EYLEA (N=287)</td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
<td>15%</td>
</tr>
<tr>
<td>Diplopia</td>
<td>7%</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>7%</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>3%</td>
</tr>
<tr>
<td>Retinal detachment</td>
<td>1%</td>
</tr>
<tr>
<td>Subconjunctival hemorrhage</td>
<td>1%</td>
</tr>
<tr>
<td>Retinal edema</td>
<td>1%</td>
</tr>
<tr>
<td>Subconjunctival hemorrhage</td>
<td>1%</td>
</tr>
<tr>
<td>Retinal edema</td>
<td>1%</td>
</tr>
<tr>
<td>Conjunctival reaction</td>
<td>1%</td>
</tr>
<tr>
<td>Conjunctival hyperemia</td>
<td>1%</td>
</tr>
</tbody>
</table>

Table 3: Most Common Adverse Reactions (≥1%) in DME Studies

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Control (N=287)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EYLEA (N=287)</td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
<td>20%</td>
</tr>
<tr>
<td>Diplopia</td>
<td>10%</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>10%</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>7%</td>
</tr>
<tr>
<td>Retinal detachment</td>
<td>5%</td>
</tr>
<tr>
<td>Subconjunctival hemorrhage</td>
<td>5%</td>
</tr>
<tr>
<td>Retinal edema</td>
<td>5%</td>
</tr>
<tr>
<td>Subconjunctival hemorrhage</td>
<td>5%</td>
</tr>
<tr>
<td>Retinal edema</td>
<td>5%</td>
</tr>
<tr>
<td>Conjunctival reaction</td>
<td>5%</td>
</tr>
<tr>
<td>Conjunctival hyperemia</td>
<td>5%</td>
</tr>
</tbody>
</table>

Adverse reactions in patients treated with EYLEA were hypersensitivity, retinal detachment, retinal edema, and endophthalmitis.
Chairman's Letter

When we started working on this issue of Managed Healthcare Executive®, we thought we would be telling you about American healthcare rebounding from COVID-19. The “new normal” has quickly become an overused cliché. But that is, basically, what we thought was ahead of us. Accommodation, adjustment, risk mitigation — all of that. Still, a sense of return.

But in July, the American experience with COVID-19 took a turn for the worse. That bouncy, optimistic rebound went awry, that purposeful sense of return curdled into an uneasy feeling. To the detriment of all Americans, everything about COVID-19 is becoming an inflamed admixture of contention and politics. Even so, there’s no question that the trajectory of the pandemic changed in late June and early July. Downward slopes in the number of cases, hospitalizations and deaths reversed and bristled with spikes in hot spots.

But American healthcare hasn’t stopped innovating — in fact, just the opposite. The pace at which vaccine candidates have been developed and put into trials is simply astounding. Urgency shouldn’t breach standards of safety and efficacy. Prioritizing who gets the vaccine? That looms as a challenge. But there is hope there, in vaccine development, not just wishful thinking.

In this issue, we discuss shifts in how American healthcare is being paid for and delivered as a result of COVID-19. Many are predicting significant increases in enrollment in Medicaid because of layoffs and the loss of employer-based insurance, and some Medicaid managed care plans have taken steps to maintain their provider networks. We’ll be keeping an eye on Medicaid managed care plans in the months (and years) ahead because of layoffs and the loss of employer-based insurance, and some Medicaid managed care plans have taken steps to maintain their provider networks.

To the detriment of all Americans, everything about COVID-19 is becoming an inflamed admixture of contention and politics. But designers and architects have ideas about how they might be reconfigured into podlike compartments to make them safer. Reengineering ventilation could also help.

Not what we were expecting
 COVER STORY

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Managed Healthcare Executive® ISSN 1533-9350, Digital ISSN 2150-7120 is published monthly by MJH Life Sciences™, 2 Clarke Drive, Suite 100 Cranbury, NJ 08512. Subscription rates: 1 year $99.00, 2 years $145.00 in the United States & Possessions; 1 year $122.00, 2 years $173.25 in Canada and Mexico; 1 year $192.00, 2 years $295.00 in all other countries. For air-expedited service, include an additional $87.00 per order annually. Single copies (prepaid only): $9.00 in the United States, $22.00 all other countries. Back issues, if available: $15.00 in the U.S.; $17.00 all other countries. Include $6.85 per order plus $2 per additional copy for U.S. postage and handling. If shipping outside the U.S., include an additional $10 per order plus $3 per additional copy. Periodical postage paid at Trenton, NJ 08650 and additional mailing offices. POSTMASTER: Please send address changes to Managed Healthcare Executive®, P.O. Box 457, Cranbury NJ 08512-0457. Canadian GST number: R-124213133RT001, PUBLICATIONS MAIL AGREEMENT NO. 40612608, Return Undeliverable Canadian Addresses to: IMEX Global Solutions, 847 Dufferin St., Oakville, ON L6M 3T8. © 2020 MultiMedia Medical LLC. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical including by photocopy, recording, or information storage and retrieval without permission in writing from the publisher. Authorization to photocopy items for internal/educational or personal use, or the internal/educational or personal use of specific clients is granted by MJH Life Sciences™ for libraries and other users registered with the Copyright Clearance Center, 222 Rosewood Dr. Danvers, MA 01923. 978-750-8400 fax 978-646-8700 or visit http://www.copyright.com online. For uses beyond those listed above, please direct your written request to Permission Dept. email: etemple-morris@mmhgroup.com MJH Life Sciences™ provides certain customer contact data (such as customer’s name, addresses, phone numbers, email addresses to) to third parties who wish to promote relevant products, services, and other opportunities that may be of interest to you. If you do not want MJH Life Sciences™ to make your contact information available to third parties for marketing purposes, simply call toll-free 866-529-2922 between the hours of 7:30 a.m. and 5 p.m. CST and a customer service representative will assist your removing your name from MJH Life Sciences™ lists. Outside the U.S., please phone 218-740-6477. Managed Healthcare Executive® does not verify any claims or other information appearing in any of the advertisements contained in this publication, and cannot take responsibility for any losses or other damages incurred by readers in reliance of such content. Managed Healthcare Executive® welcomes unsolicited articles, manuscripts, photographs, illustrations and other materials but cannot be held responsible for their safekeeping or return. Library Access: Libraries offer online access to current and back issues of Managed Healthcare Executive® through the EBSCO host databases. To subscribe, call toll-free 888-527-7026. Outside the U.S. call 218-740-6477. Managed Healthcare Executive® is a trademark of Multimedia Medical LLC. All other trademarks are property of their respective owners. Printed in the U.S.A.
**Mission**  
Managed Healthcare Executive® provides healthcare executives at health plans and provider organizations with analysis, insights, and strategies to pursue value-driven solutions.

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**John D. Halama, M.D., M.S.**, is president of the Mayo Clinic Platform and leads a portfolio of new digital platform businesses focused on transforming health by leveraging artificial intelligence, the internet of things and an ecosystem of partners for Mayo Clinic.
5 ways MCOs can address COVID-19 transmission

As we all now know, SARS-CoV-2 is an extremely communicable, novel virus with the potential for death and long-term disability that’s spread through respiratory droplets. Wearing suitably protective masks and social distancing are critical to stopping its spread. Yet a significant number of Americans refuse to wear a mask, guaranteeing the pandemic will rage on.

For managed healthcare executives, the lack of mask wearing isn’t surprising because they know how difficult it is to engage people with their own health and well-being. Those of us who work in healthcare sometimes lose track of the fact that health and healthcare are on a long list of concerns that people have: personal finances, housing, work, children, aging parents and even food — people live complicated lives. There are also those who cope with health problems by denying them.

But for health plans, getting people to care about — and be involved in — their healthcare is critical to their improved health outcomes. And for high-risk members, engagement can be a lifesaver, literally.

Indeed, care and disease management programs are a core competency critical to a health plan’s success, starting with health risk appraisals, and then identifying high-risk members and engaging them in appropriate care-focused activities.

If we’re fortunate, a COVID-19 vaccine will become available fairly soon. Still, healthcare executives must view this disease as a long-term issue. Many of them have knowledge and experience with managed care techniques that could be helpful as the pandemic drags on, such as:

- Stratification methodologies for member risk levels based on demographics, social determinants of health and health status.
- Engagement strategies that improve compliance with current guidelines from the CDC and include information on staying safe, early identification of symptoms, and minimizing the risk of transmission.
- Home care services for members with chronic conditions or COVID-19 to keep them away from hospitals, clinics and long-term care facilities where transmission could be especially harmful.
- Guidelines for mask usage and distribution of free reusable masks with easy-to-understand instructions on their use and cleaning.
- Public health messaging about the seriousness of COVID-19 and reinforcing the steps necessary to reduce exposure and transmission.

COVID-19 is now woven into the fabric of our lives, yet the consequences are unpredictable. Managed care organizations can help by stepping up and bringing to bear the expertise they have in dealing with members with chronic illness and applying it to COVID-19 care.

Hope resides in the short- and medium-term responses to the epidemic, especially in the progress being made toward the development of a vaccine. Clinicians and researchers are also making headway in the treatment of the disease. But there’s a long haul ahead, and for that we’ll need planning, implementation of those plans, an abiding sense of purpose — and each other.

Don Hall, M.P.H., and Sherry Rohlfing are principals of DeltaSigma, LLC, a consulting firm that specializes in strategic problem solving for managed care organizations.
Welcome your patients back — safely.

As practices reopen, extra precautions in patient care will be necessary. ISMIE’s Risk Management team offers guidance on risks to consider when reopening your practice — and how to mitigate them to help ensure the safety of patients and healthcare professionals.

Read the full guide at ismie.com/ReopeningYourPractice.
For decades, treatment of diabetes was largely disconnected from the treatment of heart disease, even though a person with diabetes is twice as likely to die from cardiovascular causes as someone without diabetes.

Recently, though, the paradigm has shifted: treatment. Gone are the days when diabetes drugs were judged simply on their ability to lower blood sugar. Glucose control is not unimportant, but today’s treatments for Type 2 diabetes, the most common variety by far, are expected to do much more, thanks to changes that forced the FDA to examine how diabetes drugs work.

These innovative drugs that launched within the past decade include sodium-glucose cotransporter 2 (SGLT2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists, which are powerful on their own but typically work alongside familiar drugs, including insulin.

"While SGLT2 inhibitors have been in use for years, they are increasingly being used in combination with other anti-diabetic medications like metformin and/or dipeptidyl peptidase-4 (DPP-4) inhibitors," says Matthew Sussman, vice president of modeling and strategy services at Panalgo (formerly Boston Health Economics), a health analytics company. "Additionally, innovations have been applied to GLP-1 receptor agonists, including one with an oral formulation — most others are injectable — and another for use in pediatric patients with (Type 2 diabetes)." The action hasn’t been limited to pharmaceuticals. Sussman also notes an increased focus on diet and exercise to reduce blood glucose.

Clinical trial results of several current therapies for Type 2 diabetes — including selected SGLT2 inhibitors and GLP-1 agonists — have found that the medications have a protective effect against cardiovascular disease.

For example, evidence for the clinical benefits of Jardiance (empagliflozin), an SGLT2 inhibitor, has shown that it is not only effective in treating Type 2 diabetes but also in protecting patients from future cardiovascular events.

Crisis begets opportunity

In 2006, GlaxoSmithKline’s Avandia (rosiglitazone maleate) was a blockbuster drug with annual sales of $2.5 billion. But the next year, results reported in the New England Journal of Medicine linked the drug to heart attacks, and Congress told the FDA to respond. Some scientists had long complained that pharmaceutical companies should be forced to study whether glucose-lowering drugs caused heart attacks, strokes or vascular problems. Just lowering blood sugar wasn’t enough, they argued.

The Avandia crisis gave scientists their chance. They convinced the FDA to require "cardiovascular outcomes trials," which would take years and involve thousands of patients.

The pharma companies balked at the cost at first. But in 2015, their investment paid off. A randomized, placebo-controlled trial of Jardiance showed it had protective effects against cardiovascular disease. Companies with competing SGLT2 inhibitors then tweaked their study designs to see what their drugs could do against cardiovascular disease.

Evidence from trials of the GLP-1 receptor agonists showed that they were also cardiovascular-and-diabetes twofers.

Heart failure surprise

SGLT2 inhibitors work by targeting a receptor that normally causes the body to retain blood sugar. Evidence about how they might also be protective against cardiovascular disease is still emerging.

"SGLT2 inhibitors, GLP-1 receptor agonists also tackle cardiovascular disease, renal failure."

by KEITH LORIA
disease points in several directions. The possibilities include that they lower blood pressure, have anti-inflammatory effects and improve energy metabolism of heart tissue. After the positive results for Jardiance, studies of other SGLT2 inhibitors — namely, Invokana (canagliflozin) and Farxiga (dapagliflozin) — were also shown to treat diabetes and protect patients from future cardiovascular disease events.

The big (and pleasant) surprise has been that SGLT2 inhibitors can slow down heart failure and keep patients out of the hospital. This matters to health systems because they are judged on Medicare readmissions for heart failure under the ACA.

In addition to studying the cardiovascular benefits of SGLT2 inhibitors in people with diabetes, drugmakers have also done studies to find out if these drugs worked equally well in heart failure even when patients don’t have diabetes. Stephanie Redmond, Pharm.D., CDE, founder of DiabetesDoctor.com, notes that Farxiga is now approved for treating heart failure in patients without diabetes. Recent clinical trial results mean that Jardiance is likely to get a similar sort of approval.

“The reason this is so important is that forever we have worked hard to lower blood sugars because they help reduce the risk of microvascular complications (eye disease, kidney damage, nerve damage),” says Redmond. But there is not a strong correlation that blood sugar control alone reduces your risk of heart events, she continues. “So, while controlling blood sugars helps quality of life, two-thirds of our diabetic patients die from a heart event. Now we finally have drugs that we are seeing reduce the risk of dying from a heart event in a way (that’s) different than the way they lower sugars.”

More in the pipeline
According to DelveInsight, a life science market research and business consulting firm, the diabetes market features more potential competitors to the SGLT2 inhibitors and GLP-1 receptor agonists. Consider the following:

- DWP16001 is an oral SGLT2 inhibitor under development by Daewoong Pharmaceutical Co. Ltd., a Korean company, and is currently in a phase 2 clinical trial.
- Efpeglenatide is a GLP-1 receptor agonist under development by Sanofi and in a phase 3 clinical study that’s expected to be completed by next year.

Vinita Rakheja, an editor at DelveInsight, says the Sanofi entrant uses long-acting protein technology known to be effective in Type 2 diabetes treatment. “The GLP-1 receptor agonists have the ability to suppress the release of glucagon and enhance insulin secretion in a glucose-dependent manner by binding to the GLP-1 receptor on the beta cells of the pancreas. Unfortunately, endogenous GLP-1 is degraded within one to two minutes. However, efpeglenatide has been synthetically modified for a potential once-a-month injection.”

Tirzepatide is a dual agonist to activate two receptors, the GLP-1 receptor and the glucose-dependent insulinotropic polypeptide (GIP) receptor. Eli Lilly has a trial underway that compares the investigational drug with its GLP-1 receptor agonist, Trulicity (dulaglutide). Redmond says tirzepatide is unique. Although there are several GLP-1 receptor agonists — including Trulicity, Novo Nordisk’s Victoza (liraglutide) and Ozempic (semaglutide) — tirzepatide is the only dual agonist. The addition of the GIP agonist produces additional effects on glucose and body weight and has beneficial effects on functionality of pancreatic beta cells that produce insulin.

The DelveInsight analysis predicts that tirzepatide will be successful because of its novel mechanism of action. Reviews on the drug’s effects on weight loss have also been positive. Results presented at last year’s American Diabetes Association annual meeting raised concerns about side effects. Lilly has reportedly worked on the dosing to address this.

The SGLT2 inhibitors may also get some competition from similar drugs with an added mechanism of action. Lexicon Pharmaceuticals has launched four phase 3 studies on sotagliflozin, a dual inhibitor of both SGLT1 and SGLT2 now sold in Europe as Zynquista. While targeting the SGLT2 receptor addresses most of the blood sugar normally retained in the body, adding the SGLT1 receptor as a target addresses the remaining glucose. But there is this bump in the road: The FDA previously reviewed this drug as a treatment for Type 1 diabetes along with insulin, but it wasn’t approved after a split vote by an advisory panel. Redmond says a risk of diabetic ketoacidosis — a serious condition that can be fatal — was seen in trials. In late July, Lexicon officials said they will not seek FDA approval unless they find a new marketing partner.

Keith Loria is a regular contributor who is based in the Washington, D.C., area.
Electronic prior authorization is catching on

But there are plenty of holdouts. Half of submissions are still done by phone or fax. by DONNA MARBURY

Most providers absolutely dread prior authorization. It adds to administrative work and may seem to stand in the way of good patient care. But for payers, “prior auth” is among the sturdiest, sharpest tools in the managed care toolkit because it gives them a way to control costs and steer physicians toward cost-effective choices.

Could electronic prior authorization (ePA) bring the two sides together?

“Prior authorization has not changed much in the last five years, but we have seen a shift in the method in which prior authorization requests are submitted,” says Caitlin Graham, vice president of Core Network, a division of CoverMyMeds, a healthcare technology company in Columbus, Ohio, owned by McKesson Corporation. Traditionally, the prior authorization process has been cumbersome, with providers and health plans exchanging phone calls and faxes, says Graham. It is a time-intensive process (Graham puts it rather mildly) that places a burden on pharmacists, providers, health plans and, most critically, the patient who is waiting. As ePA software becomes more accessible to providers, the hassle and wait time for prescriptions may be declining — assuming that providers are ready and willing to use the new technologies.

The COVID-19 pandemic caused many payers to suspend prior authorizations of diagnostic tests and services related to the virus. The disease has reinforced the need to minimize points of friction in the prior authorization process and take the patient out of the middle, says David Lassen, Pharm.D., chief clinical officer at Prime Therapeutics, a PBM headquartered in the suburban Twin Cities and owned by Blue Cross Blue Shield plans. “COVID-19 will likely have a transformative impact on the future as telehealth, and digital automation and tools continue to evolve to meet the rapid demand for greater efficiency and effectiveness in the process,” Lassen says.

Many large health plans have temporarily changed their policies, but the need for continued change and ePA adoption reaches beyond the current pandemic. The ePA software typically integrates directly into electronic health records (EHRs) to provide a near real-time approval for many prescription drugs. Some software providers offer portals and additional software integrations that work alongside EHR systems. As of April 2020, 14 states require ePAs and 16 states allow it. The remaining states have pending ePA legislation, according to Sure-scripts, an electronics prescription company.

“Just as COVID-19 has impacted nearly every aspect of healthcare, we have seen prior authorization requests drop at the same rate as overall prescriptions in the past few months,” Graham says. “We anticipate that prior authorization volume will return to expected levels as states continue to lift stay-at-home orders and as people begin to visit their healthcare providers for acute care.”

A domino effect

As more software is developed to make prior authorization less of an administrative burden, providers still struggle with the increased work that goes into the process. The result can be congested workflows that may, ultimately, result in poorer patient care, says Ross Moore, MBA, general manager for revenue cycle at Olive, a healthcare artificial intelligence company in Columbus, Ohio.

At a large health system, it’s not uncommon to have a team of more than 50 people responsible for
Improving Ophthalmic Care Access and Treatment Among Aging Adults

As the American population ages, chronic conditions are becoming an increasing challenge for payers. In addition to conditions such as cardiovascular disease and diabetes, eye disease is also prevalent among aging adults. Eye conditions affecting the aging population in rising numbers include diabetic retinopathy (DR), diabetic macular edema (DME), age-related macular degeneration (AMD), and others. This article will describe these conditions and explain the clinical, economic, and societal burdens associated with them. Guidelines from the American Academy of Ophthalmology (AAO) for management of these diseases will be highlighted, including current antivascular endothelial growth factor (anti-VEGF) therapy options and other treatments in development.

THE AGING OF AMERICANS

The number of individuals 65 years or older is continuously growing in the United States. This population is projected to account for 20% of Americans by 2030, and 24% by 2060. Advanced age is associated with an increased prevalence of multiple chronic conditions (MCC). According to an analysis of data from the Centers for Disease Control and Prevention's (CDC's) 2017 Behavioral Risk Factor Surveillance System (BRFSS), the prevalence of MCC (defined as the presence at least two of 12 chronic conditions listed on the survey) in the United States among those aged 45 to 64 ranged from 51% to 74%, depending on the state or U.S. territory of residence, and ranged from 69% to 86% among those 65 years or older, again depending on the state or U.S. territory of residence. Across all states and territories, the prevalence of MCC among adults aged 65 or older was significantly higher than for those aged 18-44 (P <.05). Chronic conditions included on the BRFSS include arthritis, asthma, cancer, chronic obstructive pulmonary disease (COPD), depression, diabetes, heart disease, high blood pressure, high cholesterol, kidney disease, obesity and stroke. The high prevalence of MCC among individuals in the United States aged 65 years or older suggests that resource allocation for this patient population will continue to present challenges to both health care systems and payers.

Eye diseases are also prevalent among older adults. According to a pooled analysis of data from six large population-based studies (the Beaver Dam Eye Study, Baltimore Eye Survey and Salisbury Eye Evaluation Study, Proyecto VER and Los Angeles Latino Eye Study [LALES], and the Chinese American Eye Study [CHES]), the prevalence of visual impairment (defined as visual acuity better than 20/200 but less than 20/40) among those aged 40-49, 50-59, 60-69, 70-79, and 80 years or older in the United States was projected to be 0.13 million, 0.17 million, 0.59 million, 0.99 million, and 1.77 million, respectively, for the year 2020, and was projected to be 0.16 million, 0.21 million, 0.70 million, 1.43 million, and 4.44 million, respectively, by the year 2050. For blindness (defined as visual acuity of 20/200 or less), the projected prevalence by age group was projected to be 0.11 million, 0.14 million, 0.19 million, 0.21 million, and 0.47 million, respectively, for the year 2020 and was projected to increase to 0.13 million, 0.15 million, 0.23 million, 0.32 million, and 1.18 million, respectively, by the year 2050. As visual impairment and blindness can have deleterious effects on both physical and mental health, the impact on health care spending both currently and in the future is likely to be substantial.

Eye examinations are a focal point of many quality measures and related programs, such as the Healthcare Effectiveness Data and Information Set (HEDIS), which includes a performance measure for DR screening in individuals with diabetes aged 18 to 75 years. Providers and payers who begin considering such preventative care measures now and plan in advance for the needs of the aging population will be better prepared for optimal management and effective resource allocation in the future.

THE IMPACT FOR OLDER ADULTS WITH EYE DISEASE

Eye disease can have an effect on activities of daily living (ADLs), such as dressing, bathing, toileting, hobbies, housekeeping, cooking, shopping and transportation. Poor vision is associated with a lower rate of medication adherence resulting from an inability to accurately read important information contained on product labeling. Other consequences may include emotional distress from vision loss, decreased social engagement, situational depression, loss of independence, physical inactivity, falls, injuries and an increased likelihood to be admitted to long-term care facilities (LTCFs). In addition, persons with visual impairment have higher morbidity and mortality rates compared with those in the overall population.

At the level of the health system and of society, eye disease among older adults carries financial implications. In a retrospective claims-based analysis of patients 40 years or older with visual disorders including visual impairment, blindness, AMD, cataracts, DR, primary open-angle glaucoma, and refractive errors (myopia and hyperopia), the total societal cost of eye disease for the year 2004 was estimated to be $35.4 billion (2004 USD). Components of this societal cost estimate included costs to the patient (both direct and indirect [productivity losses]) and costs to third-party payers (Medicaid and Medicare in this case). Data from the 2001 MarketScan Commercial Claims and Encounters Database, the 2002 National Ambulatory Medical Care Survey, the 2002 National Hospital Ambulatory Medical Care Survey (outpatient department file), Medicare claims data from the year 2000 (physician, outpatient and inpatient hospital files), and data from the Consumer Assessment of Health Plans Survey from a nationally representative sample of 167,993 Medicare fee-for-service beneficiaries were all utilized.

Of the $35.4 billion total paid by patients and third-party payers, $16.2 billion was attributable to direct medical costs (outpatient and pharmaceutical costs); $11.1 billion was attributable to direct non-
TABLE 1. ESTIMATED PREVALENCE OF COMMON EYE DISEASES IN AGING AMERICANS

<table>
<thead>
<tr>
<th>EYE CONDITION</th>
<th>CHARACTERISTICS</th>
<th>ESTIMATED PREVALENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataracts&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Lens clouding and opacity</td>
<td>24.4 million, 50 million</td>
</tr>
<tr>
<td>Diabetic retinopathy&lt;sup&gt;14,54&lt;/sup&gt;</td>
<td>Microvascular complications in the retina</td>
<td>7.7 million, 14.6 million</td>
</tr>
<tr>
<td>Glaucoma&lt;sup&gt;14,22&lt;/sup&gt;</td>
<td>Damage to the glaucomatous optic nerve</td>
<td>2.7 million, 6.3 million</td>
</tr>
<tr>
<td>Age-related macular degeneration&lt;sup&gt;14,27&lt;/sup&gt;</td>
<td>Damage to the macula</td>
<td>2.1 million, 5.4 million</td>
</tr>
<tr>
<td>Retinal detachment&lt;sup&gt;55,56a&lt;/sup&gt;</td>
<td>Detachment of retina from position at the back of the eye</td>
<td>30,900, 39,800</td>
</tr>
</tbody>
</table>

* 1/10,000 extrapolates to 30,900 in 2010 (US population 309 million, 39,800 in 2050 (US population 398 million).

Medical costs (nursing home care, guide dogs and federal programs for the visually impaired, including the Department of Education’s Independent Living Services for Older Blind Individuals, the American Printing House for the Blind, and the Library of Congress’ National Library Service for the Blind and Physically Handicapped); and the remaining $8.03 billion was attributable to work productivity losses. Of the $16.2 billion spent on outpatient and pharmaceutical costs, $6.8 billion was attributable to cataracts, $5.5 billion to refractive error, $2.9 billion to glaucoma, $575 million to AMD, and $493 million to DR. Of the $11 billion attributable to direct nonmedical costs, $10.96 billion was spent on nursing homes and long-term care, $62 million was spent on guide dogs, and $94 million was spent on federal programs for the visually impaired.

**OVERVIEW OF COMMON AGE-RELATED EYE DISEASES**

Table 1 provides a list of common eye diseases found in older adults and compares their anticipated prevalence increase from 2010 to 2050. The most common age-related eye diseases are cataracts, glaucoma, AMD, and DR. Cataracts involve lens clouding and opacities that interfere with vision. Without surgery, the disease can progress to blindness. Globally, cataracts account for 47% of cases of blindness. However, low- and middle-income countries carry most of this burden and developed countries contribute far less. In less-developed countries, cataracts account for 50% of blindness while it accounts for only 5% of blindness in higher income countries where surgery is much more accessible. Cataract rates increase substantially with age. According to an analysis of the 2002 Vision Health Supplement of the National Health Interview Survey (NHIS) conducted by the CDC, the prevalence of cataracts among those aged 18-44, 45-54, 55-64, and 75 years or older was 0.5%, 2.7%, 9.3%, 31.0%, and 53.4%, respectively. After adjusting for socioeconomic variables and the presence of diabetes in multivariable logistic regression models, those in the 45-54, 55-64, 65-74, and 75 years or older age groups had 3.5, 6.7, 14.6, and 29.28 times greater odds of being diagnosed with glaucoma compared with the age 18-44 age group, respectively, and these comparisons were all statistically significant (P < .05).

Glaucoma

Glaucoma is characterized by damage to or acquired atrophy of the optic nerve, causing vision impairment and ultimately, blindness. Primary open-angle glaucoma (POAG), which is chronic and slowly progressive, is the most common form of the disease. According to an analysis of the 2002 Vision Health Supplement of the NHIS conducted by the CDC, the prevalence of glaucoma among those aged 18-44, 45-54, 55-64, and 75 or older years was 0.4%, 1.3%, 2.5%, 5.7%, and 10.3%, respectively. After adjusting for socioeconomic variables and the presence of diabetes in multivariable logistic regression models, those in the 45-54, 55-64, 65-74, and 75 years or older age groups had 3.5, 6.7, 14.6, and 29.28 times greater odds of being diagnosed with glaucoma compared with the age 18-44 age group, respectively, and these comparisons were all statistically significant (P < .05).

According to a retrospective chart review of nearly 1500 patients (mean age of 71 years) with glaucoma between July 2007 and July 2010 from Duke University’s Eye Center, 13% met criteria for legal blindness (best-corrected visual acuity of 20/200 or worse in both eyes or a constricted visual field of less than 20 degrees in both eyes), 24% met criteria for monocular vision (legal blindness in one eye), and 7% met criteria for being driving restricted (visual acuity worse than 20/50 in both eyes or a constricted field of vision less than 60 degrees in both eyes). According to the NIH National Eye Institute, glaucoma affected 2.7 million Americans in 2010, and that number is expected to more than double to 6.3 million by 2050 (Table 1).

Age-Related Macular Degeneration

AMD is a deterioration of the central portion of the retina, known as the macula, which is responsible for central visual acuity and color vision. The retina is located at the back of the eye and is responsible for sending images to the brain via the optic nerve. AMD can be categorized as either dry (ie, nonexudative or non-neovascular) or wet (ie, exudative or neovascular). Dry AMD is associated with drusen, which are yellowish lipid deposits in the retinal epithelium that contain pro-inflammatory factors and inactivates the complement system. Wet AMD is characterized by formation of new blood vessels in the retinal...
TABLE 2. NOVEL OPHTHALMIC THERAPIES IN THE PIPELINE

<table>
<thead>
<tr>
<th>Agent</th>
<th>Mechanism of action</th>
<th>Intended indication</th>
<th>Trials</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abicipar</td>
<td>Anti-VEGF-A designed ankyrin repeat protein with high-affinity target binding proteins</td>
<td>Wet AMD</td>
<td>SEQUOIA62,</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CEDAR61,</td>
<td></td>
</tr>
<tr>
<td>OPT-302</td>
<td>Anti-VEGF receptor 2 and 3 molecule that blocks VEGF-C and VEGF-D</td>
<td>Wet AMD</td>
<td>OPT-3022,</td>
<td>2</td>
</tr>
<tr>
<td>Conbercept (KH902)</td>
<td>Recombinant fusion protein that binds all anti-VEGF-receptor isoforms and PlGF</td>
<td>Wet AMD</td>
<td>PANDA-1,</td>
<td>3</td>
</tr>
<tr>
<td>Ziv-afibercept</td>
<td>Recombinant fusion protein with similar actions on VEGF isoforms and PlGF as afibercept</td>
<td>Wet AMD, DR, others</td>
<td>ZALTRA64,</td>
<td>2</td>
</tr>
<tr>
<td>Faricimab (RO6867461)</td>
<td>Bispecific antibody for intravitreal use to simultaneously bind angiopeptin-2 and anti-VEGF-A with high potency and specificity</td>
<td>Wet AMD</td>
<td>STAIRWAY66,</td>
<td>2</td>
</tr>
<tr>
<td>Port delivery system</td>
<td>Ranibizumab with sustained delivery</td>
<td>Wet AMD</td>
<td>ARCHWAY58,</td>
<td>3</td>
</tr>
<tr>
<td>with ranibizumab</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RGX-314</td>
<td>One-time subretinal gene therapy</td>
<td>Wet AMD</td>
<td>RGX-31459,</td>
<td>1,2</td>
</tr>
</tbody>
</table>

AMD, age-related macular degeneration; DME, diabetic macular enema; PlGF, placental growth factor; VEGF, vascular endothelial growth factor.

...tissue, which can cause fluid buildup and/or hemorrhage, leading to fibrosis (scarring).23,24,26

According to an analysis of the 2002 Vision Health supplement of the NHIS conducted by the CDC, the prevalence of macular degeneration among those aged 18–44, 45–54, 55–64, and 75 years or older was 0.2%, 0.4%, 0.9%, 2.8%, and 8.7%, respectively.28 After adjusting for socioeconomic variables and the presence of diabetes in multivariable logistic regression models, those in the 45–54, 55–64, 65–74, and 75 years or older age groups had 2.14, 4.60, 15.97, and 51.30 times greater odds of being diagnosed with glaucoma compared to the age 18–44 age group, respectively, and these comparisons were all statistically significant (P < .05).39

Wet AMD, which accounts for approximately 10%-15% of AMD cases, is responsible for 90% of AMD-associated severe vision loss.33,37 The prevalence of AMD is expected to grow from 2.07 million to 5.44 million cases between 2010 and 2050 (Table 1).37

Diabetic Retinopathy

DR is characterized by damage to the microvasculature within the retina.28 It is broadly classified as nonproliferative (NPDR) or proliferative (PDR) based on the presence or absence of new blood vessel formation (neovascularization or angiogenesis).29,30

NPDR is characterized by microaneurysms (vessel outpouching and leaks), lipid exudates, microhemorrhages, cotton-wool spots associated with nerve fiber damage, among other clinical findings.29,30 PDR is associated with angiogenesis (growth of new vessels into the retina), hemorrhages, and retinal detachment.29,30 PDR is considered a more severe stage of DR, as it is more likely to cause vision loss.30

During advanced stages of DR, plasma can begin to leak out of retinal capillaries from a compromised blood-retinal barrier, leading to diabetic macular edema (DME), a severe complication of DR marked by swelling of the macula that can lead to severe vision loss.30,32,33 DME can develop without evident symptoms; therefore, early detection, timely treatment, and follow-up care are important to effectively treat DME and prevent blindness.30 The number of Americans with DR was estimated at 7.7 million in 2010 and is expected to reach more than 10 million by 2030 and 14.6 million by 2050.34

A severity scale known as the Diabetic Retinopathy Severity Scale (DRSS) was developed in the 1990s by the Early Treatment Diabetic Retinopathy Study Research Group (ETDRS) sponsored by the National Eye Institute (NEI) and is still utilized today in research studies, but a more abbreviated version (the Diabetic Retinopathy Disease Severity Scale [DRDSS]) was recommended in 2002 for routine, practical management of patients.30,35-37 The DRSS requires the use of photography to grade DR and is based on a numeric scale with 13 cut-points for absence of DR (score of 10) to severe DR (score ≥81).36 Some of the cut-points on the DRSS are 35 for mild NPDR, 43 for moderate NPDR, 53 for severe NPDR, 61 for mild PDR, 65 for moderate PDR, and ≥81 for advanced PDR.35,36 On the DRDSS, there are five descriptive categories: no apparent retinopathy, mild NPDR, moderate NPDR, severe NPDR, and PDR.37

In a retrospective administrative claims-based analysis of the 1997-2004 5% Medicare Beneficiary Encrypted Files (BEF), 33,735 patients with NPDR and 6138 patients with PDR were identified (mean age 75 for both groups).38 Compared with patients with diabetes without DR (n = 178,383), average Medicare payments per patient for ophthalmic care (inpatient and outpatient) were significantly higher in both the NPDR and PDR groups (P < .001 for all comparisons).38 Specifically, ophthalmic care expenditures were $990 per patient in the non-DR group, $297 per patient in the NPDR group, and $1,223 per patient in the PDR group (all dollar values inflated to 2006 USD).38 As costs per patient were significantly higher in the PDR group compared to the NPDR, if progression from NPDR to PDR could be delayed or avoided altogether, perhaps Medicare expenditures could be...
decreased in this patient population. Using data from the National Health and Nutrition Examination Survey (NHANES) 2005-2008, the prevalence of DR among those with diabetes aged 40 years or younger was estimated at approximately 29%. Using this same dataset, the prevalence of PDR and of DME among those with diabetes 40 years or older was 1.5% and 2.7%, respectively.

According to an analysis of the 2002 Vision Health supplement of the NHIS conducted by the CDC, the prevalence of DR among those with diabetes who were 18-44, 45-54, 55-64, and 75 or years older was 8.0%, 9.8%, 9.5%, 12.4%, and 9.2%, respectively. After adjusting for socioeconomic variables in multivariable logistic regression models, those in the 45-54, 55-64, 65-74, and 75 or older age groups had 19%, 22%, 49%, and 18% greater odds of being diagnosed with DR compared with the age 18-44 age group, respectively.

**EYE SCREENINGS AND TREATMENT**

**Importance of Prophylactic Screening and Early Detection**

Early detection and treatment can prevent vision loss and complications. In most cases, if the disease is identified and treated early, vision loss can be prevented. Because symptoms may not always be present at early stages, compliance with eye examination screenings may help avoid preventable vision loss. The AAO recommends that adults 65 years or older without eye disease risk factors should receive an examination by an ophthalmologist every one to two years given the increased incidence of eye disease as individuals age. Adults with Type 1 diabetes should be examined by an ophthalmologist within five years of onset of the disease and then at least annually; those with Type 2 diabetes should be examined at diagnosis and then at least annually. Adults with acute or chronic disease may require eye examinations with frequencies ranging between hours and months, depending on the nature of the condition.

**Eye Examination Adherence**

Lack of ophthalmic monitoring and treatment can result in poor clinical outcomes, such as blindness; therefore, it is important to learn why patients do not always adhere to recommended eye examination schedules. Adherence to recommended examination schedules is low: approximately 50% of Americans with diabetes receive annual eye examinations, and the percentage among underserved and minority populations averages just 10% to 12%. Results from a 2015 cross-sectional study showed that 52% of patients with glaucoma (n = 121), 33.7% of those with AMD (n = 86), and 30.3% of those with DR (n = 33) failed to reschedule a missed appointment within a month of the recommended follow-up date. Most patients in the study were white (61.6%), privately insured (72.1%) and college educated (76.7%). The mean age of those with poor adherence was 70.5 years (SD = 14.3). Primary reasons for poor adherence to follow-up care involved a low level of understanding of the disease, legal blindness and difficulty taking time off from work. This issue of adherence to recommended eye examinations can be addressed in several ways, such as by increasing patient education and networking opportunities with fellow patients, offering affordable transportation services, improving clinical efficiencies, and increasing access to services remotely through telemedicine and similar means.

**TREATMENT RECOMMENDATIONS**

The American Academy of Ophthalmology recommends surgical procedures for cataracts, glaucoma, and DR, using the following specified procedures. For cataracts, small incision phacoemulsification with foldable intraocular lens implantation with either a biaxial or coaxial approach is recommended. For primary open-angle glaucoma, effective medical, laser, and incisional surgical approaches for lowering intraocular pressure are recommended. For DR, recommendations call for laser photoocoagulation surgery for noncenter-involved DME and pan-retinal photoocoagulation surgery for PDR.

Pharmaceutical options as first-line treatment for wet AMD and center-involved DME with vision loss include anti-VEGF agents. Anti-VEGFs have reduced the incidence of AMD-induced blindness by nearly 50% in some countries. Early detection and treatment are critical for optimizing outcomes with anti-VEGFs. The anti-VEGFs aflibercept, brolucizumab, and ranibizumab are approved by the FDA for use as intravitreal treatment of retinal problems to improve or maintain vision.

Further innovations in treatment for eye disease are expected in the future. Understanding genetic components to therapy response will help individualize treatments for better results. Single nucleotide polymorphisms in genes may influence treatment response in wet AMD. Meanwhile, clinical trials are ongoing for current anti-VEGFs. CAN-TREAT is reviewing ranibizumab dosage and extended frequency for wet AMD. LUMINOUS is a 5-year outcomes-related trial of ranibizumab for wet AMD and other eye diseases. RIVAL compares aflibercept and ranibizumab with a treat-and-extend regimen for AMD. Several other new therapies for eye diseases are also in the pipeline (Table 2).

**CONCLUSIONS**

There is growing concern regarding eye disease among older Americans. Early detection and treatment are critical. The use of effective therapies is important, beginning with helping patients to adhere to recommendations for screenings, eye examinations, and treatment. Such initiatives can improve outcomes for patients and reduce costs for the health care system. They also can improve quality measure outcomes and ratings for providers and practices. Just as population health executives are preparing for increases in the prevalence of health conditions such as cardiovascular disease, diabetes, and cancer among aging adults, executives must also consider the growing impact of eye disease and plan for the onset of an increasing clinical and economic burden from visual conditions as the population ages. Being prepared with strategies to manage these conditions will allow for optimization of resources and outcomes.

References available online at ManagedHealthcareExecutive.com
Electronic prior authorization is catching on

Pharmacy/Formulary Development

Continued from Page 10

Managing the prior authorization process, notes Moore. Even then, backlogs occur and have a domino effect that may delay patient care, hinder quality and reduce patient satisfaction, he says.

Physicians are not fans of prior authorization. In a 2019 survey of 1,000 practicing physicians conducted by the American Medical Association, more than 90% of respondents said prior authorization had a negative clinical impact and 28% said it led to a serious adverse event, such as death, hospitalization, disability or permanent bodily damage.

PBMs are increasing the number of drugs they are excluding from their national formularies — formularies that the PBMs’ clients don’t necessarily follow but do set a standard. Exclusions make prescribing difficult when providers aren’t able to get real-time prior authorization results, Lassen says. Often, patients are stuck with dealing with the prior authorization process and finding out which drugs are both covered and affordable. “Practitioners don’t have sufficient information available to them at the time of prescribing or point of care,” observes Lassen. “They should, he says, be able to identify a drug’s formulary status, utilization management criteria, cost and alternative covered therapies. Because of that lack of information, patients typically find out at the pharmacy that the drug is not covered or requires a prior authorization.” Unfortunately, that puts the patient in the middle of the situation and needing to go back to the practitioner to seek a prior authorization request,” says Lassen.

Struggles with ePA use

Although nearly all pharmacies, payers and EHRs have access to ePA in one form or another, half of prior authorizations are still submitted via telephone or fax, according to 2018 payer data collected by CoverMyMeds.

“Although the industry has moved readily to ePAs, most prior authorizations are still not fully automated, but this is the goal,” Lassen says. “With the increased use of prior authorizations for specialty and high-cost medications, the volume of work has potentially become harder.”

One reason providers avoid starting prior authorization requests at the point of prescribing is because they don’t trust the plan formulary information supplied in their EHRs, Graham says. According to CoverMyMeds’ 2020 Medication Access Report, 60% of practitioners report that they only sometimes trust the insurance data available in the EHR and 19% reported they rarely or never trust this information.

Another issue that providers face in increasing ePA adoption is the multiple platforms within a healthcare setting and their interoperability. “As many software and EHR integrations take place, it can be harder for practitioners to work on multiple platforms unless there is full integration into the workflow,” notes Lassen.

Graham says CoverMyMeds works directly with system vendors to develop integrations, making access to its ePA software easier. Streamlining the most common prior authorizations could lessen the technology and administrative burden. According to Moore at Olive, part of the service that his company provides is an upfront determination if prior authorization is required. The company then helps facilitate authorization requests, frequently checks their status and manages prior authorization denials by automatically making appeals for procedures that have already been pre-authorized but were denied. Moore says that making prior authorization systems more efficient helps to improve the overall satisfaction of patients.

Earlier this year, America’s Health Insurance Plans (AHIP), the trade association for the health insurance industry, launched the Fast Prior Authorization Technology Highway (Fast PATH) program to assist providers in adopting ePA. Fast PATH utilizes the technology of Surescripts, owned by CVS Health, Express Scripts, the National Association of Chain Drug Stores and the National Community Pharmacists Association. As AHIP pitched it in a press release, when medications are ordered through the EHR, Fast PATH gives prescribers immediate access to patients’ pharmacy benefits so they know whether the prior authorization is required and have information about alternatives. And if the doctor prescribes a medication that does require prior authorization, he or she can immediately submit the approval request through the EHR.

Lassen says his company is also jumping on the ePA bandwagon and investing in strategies and tools that will serve up information at the point of care, including real-time benefit check, alternative drugs, cost comparison and the ability to auto-approve prior authorizations. “Our objective is to limit any friction to our providers and members and ensure people get the medicine they need to live healthy lives,” Lassen says.

Moore says one of the obstacles to a more streamlined approach to prior authorizations is the lack of uniformity. “There must be greater collaboration between payers and providers to set universal guidelines on requirements, starting with the high-volume, low-complexity procedure types that consume the greatest administrative cost across the healthcare continuum,” says Moore.

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Expensive, brand-name biologics have become an important part of American cancer treatment. If biosimilars are ever going to live up to their billing and put a serious dent in the spending on, and cost of, biologics, they’re going to need to win over a considerable number of hearts and minds in organized oncology. That may be beginning to happen.

“It is really only recently — the last year, year and a half that they have become practically, pragmatically available,” says Wui-Jin Koh, M.D., chief medical officer of the National Comprehensive Cancer Network, an alliance of 30 leading cancer centers headquartered in suburban Philadelphia that issues influential treatment cancer guidelines. “Can we say it is a success?” says Koh about biosimilars. “I think I can say it has been an emerging success in terms of approvals and availability. It may not be the same success in terms of utilization.”

Gary H. Lyman, M.D., M.P.H., a professor at the Fred Hutchinson Cancer Research Center in Seattle and past chair of the American Society of Clinical Oncology Biosimilars Work Group, noted that most of the approved biosimilars in the U.S. have been on the market for only the past one to two years. “It’s a period far too short to fully understand the impact on drug pricing,” said Lyman in an emailed response to questions.

Lyman said the experience with generics suggests that it often takes multiple competitors in a drug class before prices start coming down. “We do have some early evidence that the price associated with supportive care biosimilars has begun to decrease with multiple biosimilar competitors,” he said. Of 28 biosimilars that the FDA has approved, 16 have indications related to cancer, nine for treatment and seven for supportive care.

Koh says an NCCN steering committee voted unanimously in May to revise all of its guidelines to indicate that an FDA-approved biosimilar is an “appropriate substitution” for a brand-name biologic. Previously, some of NCCN panels for specific cancers had endorsed substitution. Koh says more “real-world” data will need to be collected on biosimilars as they enter clinical practice to precisely evaluate their equivalency to their brand-name products. But he said that he doesn’t have doubts about biosimilars. “For all intents and purposes, the efficacy, the safety, cannot be distinguished from the reference product,” says Koh.

Lyman concurs. He said he is “very confident” that biosimilars are highly similar and as effective as their reference products and that he is “perfectly comfortable” using the biosimilars of cancer treatment drugs. But he observed that clinicians tend to be warier of the biosimilars for treatment than the ones for supportive care. That’s understandable, said Lyman, but with careful monitoring, there should be no greater concern about the treatment drug biosimilars. Drift — unplanned changes to biosimilars that may affect their efficacy — is a concern, but in Lyman’s view drift can happen to both biosimilars and their reference products.

Koh says NCCN does not have a specific policy about whether clinicians should inform cancer patients that they are prescribing a biosimilar. But he says the organization does have general recommendations that “clinicians, in dealing with patients, should be fully transparent.”
Amazon’s quiet, selective forays into healthcare

Whether the online giant has larger healthcare ambitions is unclear.  by DEBORAH ABRAMS KAPLAN

PillPack, Amazon Care, Haven, Amazon Comprehend Medical, and yes, Alexa. This is not an exhaustive list, but these are some of Amazon’s forays into healthcare and its one-fifth share of American gross domestic product. The Seattle-based online retailer has also become an infrastructure company with major market positions in logistics and cloud storage. Predictions that Amazon would be transforming American healthcare perhaps shot too high, but healthcare is very much on its agenda.

Although it’s impossible for Amazon to operate in total stealth mode, the company hasn’t shared a sweeping vision of its healthcare strategy publicly, although analysts and reporters do pick up nuggets here and there from earnings reports and company press releases. When Bryan Niehaus, vice president of Advis, a healthcare consulting firm in Mokena, Illinois, looks at Amazon’s various entry points into the industry, it shows him that the company is perusing and being selective. “They’re learning about the healthcare industry and picking their spots on where to get involved. Some areas might be disruptive, some are extensions of their current business,” Niehaus says.

The potential disruption may result from attempts by Amazon Care and Haven (although Haven has struggled to find its footing) to provide direct patient care and influence quality and cost. Extensions of their current business includes PillPack, a consumer prescription delivery model, and the various data storage and analytics efforts.

PillPack
Amazon bought PillPack in 2018, when it was already a full-fledged mail-order pharmacy able to dispense in 50 states, with local brick-and-mortar pharmacy relationships. Amazon has a Midas-touch image, but that talent isn’t always so homegrown. “Not everyone thinks of Amazon being innovative in mergers and acquisitions,” says Nathan Ray, director of healthcare mergers and acquisitions at West Monroe, a business and technology consultancy headquartered in Chicago.

PillPack had not only a growing business model, but also the regulatory expertise Amazon needed to get into the pharmacy business. They had the licensing and the infrastructure to supply retail pharmacies and mail-order services. “Clearly they saw the opportunity to break into this large market and connect to their existing consumer base,” says Niehaus. PillPack has the potential to be a digital front door for customers to add to the goods and services Amazon offers. “Maybe they can partner with a large electronic health record (EHR) system and have a sign-on space,” he says. This could allow them to consolidate across prescriptions, medical devices or other medical supplies.

Blue Cross Blue Shield of Massachusetts announced a deal with PillPack in December to offer the pharmacy services to plan members, including free delivery of multiple medications. In its press release, the Massachusetts Blue plan said it was the first health plan to offer “direct integration” with the PillPack’s services.

Another possible fit with PillPack, say Niehaus and Ray, is telehealth services. “The possibilities are wide in how they can approach and streamline disparate parts of the health system,” Niehaus says.

Aside from Amazon Care, which currently serves some Amazon employees and their dependents in Seattle, the company doesn’t offer its own telehealth services. But that doesn’t mean Amazon is a total bystander. A large fraction of the telehealth services launched amid the COVID-19 pandemic use
Amazon’s quiet, selective forays into healthcare

Amazon Web Services (AWS) data centers, notes Ray. The connection between telehealth and AWS is a reminder that almost anything having to do with the internet is a business opportunity for Amazon. Combine telehealth with the data collection and analysis from wearables and remote monitoring, and this could be the biggest healthcare change of our lifetime, says Ray. Amazon has made advances in technology-enabled care, but “I would have expected them to move faster,” in terms of telehealth, he adds.

Amazon Care

In September 2019, months before the COVID-19 pandemic whetted appetites for virtual healthcare, Amazon took the prescient step of launching Amazon Care, a virtual health program offering telehealth visits and in-person follow-up care to a subset of Seattle headquarter employees. Among the eligible employees are those living in 105-designated ZIP codes with Amazon-sponsored health plans (as opposed to those with Kaiser Permanente plans). Vin Gupta, M.D., a pulmonologist and high-profile public health expert, was hired in January as principal scientist. In February, the endeavor was expanded to include employees at its warehouses and subsidiaries across the country. Large, self-insured employers actively participating in employee health management can get better value and offer more services than companies with commercially insured plans. The Amazon Care model could be extended to other sites across the country or even to other companies.

Haven

Amazon Care’s primary care clinics could become a great proving ground for healthcare innovation. The prospects for Haven are perhaps cloudier, especially considering the once sky-high expectations that surrounded the enterprise. Launched in January 2018, Haven is a joint effort of Amazon, Warren Buffett’s Berkshire Hathaway and JPMorgan Chase. Healthcare’s chattering class was talking about the “Amazonification” during its perinatal period. The naming of Atul Gawande, M.D., as CEO of Haven added cachet.

But Gawande announced in May that he was stepping down as CEO. The Haven website says its goal is to pursue “a number of common-sense fixes, as well as innovative approaches, to address issues like making primary care easier to access, insurance benefits simpler to understand and easier to use, and prescription drugs more affordable. We are looking at new ways to use data and technology to make the overall healthcare system better.” Those are admirable but middle-of-the-road objectives. “They’re encountering some existential questions about how they go about effecting change,” says Niehaus. “What is Haven’s true goal? Cutting costs in healthcare is a wide one. How they’ll go about doing so hasn’t become clear at this point.”

So far, Haven has only one concrete achievement: Working with Cigna and Aetna, employees at JPMorgan were offered plans with more price transparency.

Amazon Comprehend Medical

Comprehend Medical, an outgrowth of AWS, is a natural language processing and artificial intelligence (AI) service. It’s complicated to pull data out of medical records because EHR systems were developed more for billing than data capture and clinical analysis. Amazon is offering not only transcription services that put the data into the appropriate fields but also data standardizing to healthcare clients so they can better access and use their data. AI is also used in imaging studies to identify potential abnormalities, but algorithms are developed for specific-use cases, making it a slow process to develop new functionality. “These concepts are valuable but incrementally being brought into how things work,” Ray says.

Alexa

Anthem Blue Cross and Blue Shield of Ohio recently announced that Alexa, Amazon’s smart speaker, could be used by members to refill prescriptions, schedule appointments and answer insurance-related questions about claims and

...
deductibles. “The larger trend here is, how do we simplify the experience for our members?” says Rajeev Ronanki, Anthem’s chief digital officer. Anthem offered the service for informational questions starting in 2018, providing the nearest doctor or pharmacy information without Alexa identifying the user. “Once the technology partners like Amazon got HIPAA certified in 2019, we started looking into more specialized services,” he says.

National Health Service in Great Britain partnered with Amazon for Alexa to provide general health guidance in 2019. Niehaus wonders out loud whether the Alexa of the future would prompt users on what purchase to make based on the questions she is asked.

Data and security
With so many points of entry into Amazon’s data reach, the natural question is how are they using the collected data? In the context of the deal with National Health Service, Amazon told The New York Times that the company was not building health profiles or using health information to recommend or sell products. The devices record what is said, however, and there have been cases of the smart speakers sending recordings without user consent. Amazon also retains recordings to help train its AI algorithm. Ronanki says that Alexa is not storing any member information. “We’ve verified that through our contract,” he says. Alexa authenticates the member’s voice to ensure it’s the right person, and Amazon sends a passkey to the user’s phone for each unique conversation. The resulting action is confirmed, like a scheduled appointment or prescription refill, based on the member’s stored preferences.

However, even without retaining health data, Amazon can use the lessons learned from the experience to develop systems for other organizations, Niehaus says. Amazon will have, for example, access to all the information gleaned from the entire British population that can be applied elsewhere. But there are clear restrictions about which data Amazon can access from healthcare organizations using AWS, precluding Amazon from mining that data. “It’s fairly common for cloud services to host data in accordance with HIPAA. There’s no evidence they’re inappropriately accessing the data,” says Niehaus.

The bigger concern for Ray is the potential consumerization of the healthcare data for marketing purposes. “One of the largest areas of healthcare is marketing, especially around Medicare Advantage. Do I worry about what data they’re mining about my parents,” resulting in targeted ads? Yes, he says.

Where does Amazon go from here?
Amazon’s future in healthcare may partly depend on how the entrenched players respond, says Niehaus. With continued industry consolidation, other players are building market share. With COVID-19, there’s been an accelerated focus on catering to patient convenience, and the relaxation of regulations has helped telehealth take off. Amazon may be on the sidelines now, and telehealth company valuations are high so there’s no bargain to be had. But Amazon bought its way into mail-order pharmacy when it bought PillPack. It could do the same with the purchase of a telehealth company.

Amazon’s overall healthcare strategy still hasn’t come into focus. “It’s unclear if there’s one person directing all the efforts,” says Niehaus, adding that he isn’t sure if Amazon will try to serve as a connection point or focus on specific healthcare services. From a mergers and acquisition perspective, says Ray, the challenge for Amazon is integration: how to fit together the various technologies.

Amazon has an opportunity now to acquire other companies that are short on capital because of the pandemic. That could be a company complementing PillPack — a competing supplier, for example. With more healthcare migrating to the home due to the COVID-19 pandemic, wearable devices and remote monitoring are likely to become more important. “The hub around your health,” says Ray, “will probably answer to the name Alexa in the not-so-distant future.”

Deborah Abrams Kaplan is a regular contributor to Managed Healthcare Executive.
It was going to be new and a bit strange. But American healthcare was leaning into a return to COVID-19 version of normal. Then cases, hospitalizations, deaths — they started to rise.

So now, a round of adjustments to the adjustments, tweaks to the tweaks. Still, pieces of new coronavirus normal are falling, Tetris-like, into place. The payer mix is shifting: less employer-based coverage, more Medicaid. The waiting room (chairs, dog-eared magazines) is a relic, temporarily replaced by arrangements like airport cellphone lots.

Social and business norms are being suddenly consigned to the past. The firm handshake? No way! Healthcare executives are experimenting with replacements.
The new normal, interrupted

U.S. healthcare was gearing up for a rebound that includes telehealth. But then the pandemic surged back. **BY JARED KALTWASSER**

Don’t bother asking Keith Blechman, M.D., when his practice will get “back to normal.”

Operations at his Upper East Side plastic surgery practice in Manhattan have shifted so drastically in the months since the COVID-19 pandemic began that the bygone era of “normal” seems hopelessly anachronistic. “There’s nothing not normal about this,” he said. “This is just how things are.”

It’s not that things aren’t changing for Blechman and his practice. Just about everything has changed. It’s just that he sees little chance that his business will revert to where it was, and in many ways he’s glad it won’t. “There are a lot of things I don’t want to go back to, to be perfectly honest with you,” he says. “This has been a great way to reset and pick the things I wanted to integrate.”

Don’t call it “the new normal.” The optimists speak of embracing change and their silver-lining playbooks, while their less-sunny counterparts see enormous uncertainty that is hard to get your head around.

But July stress-tested the optimists (and many others, but maybe especially the optimists). After dipping to lows in late June and early July, the number of COVID-19-related hospitalizations and deaths shot back up as outbreaks flared up in Texas, Arizona, California and elsewhere. The Atlantic’s COVID Tracking Project counted 306 deaths on July 4. On July 29, the tally was 1,418, a roughly fourfold increase. Providers hoping for quick rebound had to lower their expectations, and payers with large profits and margins because of lower expenditures had to defend their relative good fortune. One analysis predicted that without further government support, half of all the country’s hospitals will operate in the red this year. The New York Times science reporter Donald G. McNeil Jr. described the U.S. as a “wounded giant” and characterized the mood of the 20 public health experts the newspaper interviewed as sad and exhausted: “While once there was defiance, and then a growing sense of dread, now there seems to be sorrow and frustration.”

**TELEHEALTH’S MOMENT**

Blechman continued normal operations until March 13. By the following week, he and his staff were working from home, inasmuch as they were “working” at all. He had lots of company. A report released by Fair Health in June showed that utilization of healthcare professional services plummeted by 65% year over year in March and that revenue fell by an estimated 45%. The drop-off in April was even worse, with utilization and revenue falling by 68% and 48%, respectively.

Telehealth has been a port in the storm — one of the few ways providers were able to provide some services and bring in some revenue amid the pandemic. Findings like those from a McKinsey & Company consumer survey are rife. In 2019, about 1 in 10 U.S. healthcare consumers reported using telehealth, according to the consulting firm. By late April that proportion had grown to about 1 in 2. On the provider side, McKinsey found the number of telehealth visits jumped between 50-fold and 175-fold across health systems, practices and other providers.

Marlena Kane, M.P.H., associate administrator of consumer solutions and access at the University of Southern California’s Keck Medicine, says the acceleration of telehealth amid the pandemic had a running start.

“ ’It’s not that people didn’t have telehealth platforms before this happened,” says Kane. “Systems have been trying to do this for quite some time, so most people have platforms already.”

Uncertainty about payment and a prevailing opinion that in-person visits were better in almost all domains kept telehealth in holding pattern. But amid the pandemic, CMS and private insurers shifted reimbursement policies, and provider and patient views about telehealth’s inferiority changed the same way that attitudes about working from home have shifted. In late July, the COVID-19 public health emergency was extended for another 90 days, so the pandemic status quo won’t be disrupted for another couple of months. Kane says the prospect of going back to pre-pandemic reimbursement rates for telehealth is scary. “Not everyone has access to telehealth, and it does create some questions around social equity,” she notes. “But for those that do and can have (access to telehealth), it has prevented a lot of gaps in care that might not have been prevented otherwise.” Kane expects
high levels of telehealth utilization to continue, including in ways that hadn’t previously been conceived.

Sri Bharadwaj, M.S., vice president of digital innovation at Franciscan Health, an Indiana-based health network, said one COVID-19-related change his hospitals have implemented is an overhaul of multispecialty rounding. Instead of making individual rounds, patients’ teams of specialists now gather in a conference room while one care team member takes an iPad attached to an IV pole to the patient’s room. Using the iPad, all a patient’s specialists can “visit” at the same time, cutting down patient interruptions and decreasing the odds of gaps or miscommunications. “It changes the way care is delivered to the patient on the inpatient side,” he says. While this new way of rounding was born out of necessity, Bharadwaj says it is here to stay at his hospitals.

The expanded use of telehealth for specialist care could be particularly important because specialists have seen huge drops in patient visits. Oral surgery was the hardest-hit specialty, according to the Fair Health report, with utilization dropping by 80% year over year in March and 81% in April.

Now the question is whether healthcare utilization (and expenditure) will come back. The answer: It will because after the cliff dive of the second quarter, the only way is up. Perhaps the better question to ask is by how much. A June report by the financial consultancy Kaufman Hall said that the operating margins of U.S. hospitals increased to 4% in May, though the report noted that the positive result was only possible thanks to government aid through the Coronavirus Aid, Relief, and Economic Security Act.

Humana CEO Bruce Broussard said at a virtual meeting in late June that his company has seen roughly a 15% drop in inpatient and outpatient volume compared to a normal year. Consistent with Fair Health and Kaufman Hall reports, Broussard said volume dropped markedly in March and April before coming back somewhat in May. He expected volume to continue to ebb and flow in the coming months.

“We continue to believe over a period of time that we will see the continued normality of the care,” he said. “I think it will go in spurts because of threats, of waves and other things.” Broussard said he’s hopeful that by the end of the year the industry will “get back to normality.”

But that was in late June, before July brought a rebound of cases, hospitalizations and deaths that seemed to push the U.S. back into the throes of the pandemic.

INTO THE UNKNOWN

But adjustment and innovation continue. At his plastic surgery practice, Blechman says he reevaluated every expense and shifted to a model of virtual pre-surgery consultations. As of early July, he had a waiting list of 75 patients. Those virtual visits have opened up new opportunities. He’s considering opening a second office in California, so he can hold virtual consults with patients from his home office in New York and then fly to California to perform the actual procedures. “It’s just sped along what I always wanted to do,” he says.

Yet, from a revenue standpoint, Blechman is still operating in the dark. Asked if the streamlining, the move to telehealth consults and potential business expansion would leave his practice financially whole, he says the question is impossible to answer. “I can tell you in three months.”

Jared Kaltwasser is a healthcare reporter based in Iowa.
Whether COVID-19 is going to tip the American economy into a long-lasting, full-fledged downturn is still uncertain. The economy contracted at a record rate during the second quarter, and the number of Americans receiving unemployment started to climb again in July.

Of course the state of the economy and job loss is going to affect health insurance coverage and may tip the balance toward public payers. Going into this year, enrollment in Medicaid was flat, mainly because of the strong jobs market. But the Kaiser Family Foundation (KFF) reported in late July that enrollment in Medicaid managed care started to climb in March in 16 states reporting enrollment data and that the median growth rate between March and May was 4.7%.

An earlier KFF report said that as many as 27 million Americans might have lost employer-based health insurance because of COVID-19 — and that was before July when cases, hospitalizations and deaths started to increase, waylaying hopes that the pandemic’s grip on the economy would loosen. The foundation’s experts estimated that about 80% of the newly uninsured would be eligible for Medicaid and roughly 6 million for an ACA exchange plan. The report also predicted that a growing number of Americans will fall into the coverage gap, making too much to qualify for Medicaid but not enough to receive ACA subsidies.

According to a KFF health tracking poll in May, 31% of the households that have lost income because of COVID-19 said it is very or somewhat likely that they will turn to Medicaid for health insurance coverage in the next year.

John Baackes, CEO of L.A. Care Health Plan, the largest publicly operated health plan in the country, is daunted by the fact that 1 in 3 Californians were covered by Medi-Cal, the state’s Medicaid program, before the COVID-19 pandemic. When an economic downturn occurs and revenues flowing into state government coffers slacken, cuts to Medicaid tend to follow, threatening safety net providers. “This is putting a lot of providers out of business, leaving a hole in the safety net,” says Baackes. California state officials contemplated some deep cuts to Medi-Cal programs to help patch a $54 billion deficit in the state’s 2020-21 budget, but eventually deals were struck that found the money elsewhere and Medi-Cal escaped relatively unscathed.

One thing that concerns Baackes is the 45- to 60-day waiting period once someone who is unemployed applies for Medicaid — because eligibility is determined by county social services, not by individual plans. L.A. Care and 26 other plans are standing behind a ruling for presumptive eligibility — immediate access to healthcare while applying for regular Medicaid or COBRA. Barring extension of unemployment benefits, the KFF report predicted that by the beginning of next year nearly 17 million more Americans will be eligible for Medicaid and roughly 6 million for an ACA exchange plan. The report also predicted that a growing number of Americans will fall into the coverage gap, making too much to qualify for Medicaid but not enough to receive ACA subsidies.
Impact Analysis: The COVID-19 Medicaid Surge

**Healthcare Executive**, says surveys of the association’s membership, which includes 76 health plans sponsored by community health centers and other safety net providers, show that they expect their enrollment to grow by 5% to 10% because of the COVID-19 pandemic, which would higher than the median growth rate reported by Kaiser. However, Murray says it is too soon to tell whether reality is going to match up to those expectations, partly because of the lag between when people get enrolled in Medicaid and membership in managed care health plan.

Murray’s group announced in June that it was launching a six-figure campaign on Google designed to direct people to healthcare.gov, the website for ACA exchange plans and Medicaid information, when they search on terms like unemployment and health insurance. “We would certainly encourage the administration to be more vocal that Medicaid is out there,” says Murray, adding that her group has also been concerned that the enrollment period for the ACA exchange plans was not extended.

Like for-profit insurers, Murray’s members saw a precipitous drop utilization this spring and therefore a decline in their medical expenditures. Partly out of concern about maintaining provider network, health plans have “tried to get money out to their providers as opposed to giving it back to the states,” says Murray (if their medical-loss ratios get too low, Medicaid managed care must return funds to the states they contract with). The plans have gotten money to providers by loosening their prior authorization rules, moving some providers to capitation payment, and awarding quality bonus money in advance, according to Murray.

**THE ROLE OF MEDICAID**

“Medicaid is the biggest public health responder to the pandemic, making it especially amenable to changes states need to put in place during (the COVID-19 pandemic). All features make it the go-to program today,” said Sara Rosenbaum during a webinar series co-sponsored by The Commonwealth Fund. Rosenbaum is a professor at Milken School of Public Health at George Washington University.

She said that as a “matter of policy,” flexibility is Medicaid’s primary attribute because despite some administrative issues, it has no special enrollment period; people can enroll at point of care or when they need coverage, and the federal government can send money out the door when needed.

“Changes can be made rapidly,” Rosenbaum said, making it “much less cumbersome than in the commercial marketplace.”

“Medicaid’s retainer payment policy is the fastest way to transfer funds and allows states — once they address the formula issue — to rapidly draw down funds at an enhanced rate of payment versus a grant program for healthcare providers,” she said.

**AN EXPENSIVE PROGRAM**

Medicaid, however, is also one of the largest, if not the largest, budget item for states. Its countercyclical nature — spending and enrollment typically rise during economic downturns when revenues drop — a dilemma for state budget officials.

“States have limited options to reduce spending,” says Robin Rudowitz, vice president at KFF and co-director for the Program on Medicaid and the Uninsured. “In prior downturns, states have turned to provider rate cuts and maybe restricting optional benefits, but given provider fiscal stress, these are not easy options. States cannot restrict eligibility as a condition for receipt of the additional Federal Medical Assistance Percentage (FMAP).”

The FMAP is computed from a formula that takes into account the average per capita income for each state relative to the national average (poorer states have a higher match). By law, the FMAP cannot be less than 50% and is currently 90% for expansion states.

“Because of the match, states need to make bigger program cuts and lose federal aid to save state dollars,” she says. Medicaid is funded from both federal and state funds, so states need to make substantial cuts to Medicaid to generate state savings. For example, if a state has a 50% match rate, a $100 cut to Medicaid will reduce state spending by $50 and federal spending by $50.

**ENROLLMENT AND EXPENDITURES**

Medicaid enrollment between 2020 and 2021 is expected to grow from 76.7 million to 77.6 million. From 2018 to 2027, the total number of Medicaid enrollees is projected to increase about 1.1% per year. Expenditures will rise from $672.5 billion to $709.2 billion between 2020 and 2021. The average federal share is 62%. However, these estimates were made prior to the pandemic.

Total Medicaid expenditures (federal and state combined) for benefits and administration are projected to top $1 trillion by 2027, while federal spending on Medicaid is projected to reach $624.8 billion that year, according to CMS. The largest expenditures are for capita payments and premiums.

Baackes says his plan has 230,000 lives and is seeing more people applying for CalFresh, California’s food stamp program, than for Medicaid. However, he anticipates that enrollment in L.A. Care will increase incrementally by 10% to 12% over the next several months due to the current recession.

According to a KFF poll of 38 responding states, nearly all those with enrollment projections and more than half with spending projections anticipate 2020 growth rates to exceed pre-pandemic estimates. Nearly all states with FY 2021 (fiscal year begins July 1) projections in enrollment and spending expect growth rates to exceed FY 2020.

The beginning of FY 2020 painted very different picture: States anticipated flat enrollment growth due in part to changes in renewal processes and new functionality of upgraded eligibility systems.

Mari Edlin is a freelance journalist living in Sonoma, California.
New ways, new places for healthcare’s waiting room

Many providers are asking patients to wait in their cars. In the future, the waiting room could be divided into small, pod-like rooms.

BY AINE CRYTS

Patients probably won’t be flipping through issues of People and Reader’s Digest in waiting rooms this fall or even next year. The magazines will disappear, as may the decor and soft lighting that are supposed to keep patients relaxed. To keep patients and staff safe from COVID-19, many hospitals, clinics and medical practices are currently directing patients to wait in their cars before their doctor appointments.

Although the cellphone-lot version of the waiting room may work to reduce the transmission of SARS-CoV-2 in the short term, some experts question if this change could result in patients feeling less connected to their care providers, and most experts predict that patients will return to waiting rooms in the future. That means healthcare executives will need to find funding in their already tight budgets.

So what will waiting rooms of the future look like? Word to the wise: They will likely bear little resemblance to the crowded, even cozy spaces that patients have gotten used to.

WAITING IN THE CAR

The parking lot is the new waiting room at Valley Community Healthcare, a federally qualified health clinic in North Hollywood, California. Paula Wilson, the clinic’s CEO, says that signs guide patients to the parking area where they wait and that the parking area is organized by the departments where patients will be seen: a pediatrics parking area for pediatric patients, a women’s services parking area for patients being seen in the women’s services department and so on.

Patients are escorted from their cars into the exam room in the appropriate area by a staff member. Patients provide intake information on web-based forms on their smartphones; pens to fill out old-fashioned paper forms are used just once and then given to patients. Foot traffic through the clinic’s buildings is organized in a clockwise fashion, and signs guide patients to reduce the chance of people crossing paths and coming into close contact.

Wilson says she’s currently working with an architecture firm on a variety of plans, including the construction of outdoor cabanas for triaging patients before they enter the clinics. That’s a viable option in sunny, clement Los Angeles. If hospitals and clinics in the Northeast and the Midwest are going to add outdoor spaces, those structures will need to keep out the winter cold and snow.

Chris Cooper, M.H.A., a managing director at the Atlanta office of the accounting and business consulting firm BDO, observes that patients living in more densely populated areas such as New York City often rely on public transportation to get to their medical

What’s not going to work in waiting rooms, however, are the plexiglass shields now being used in stores that separate cashiers and shoppers, says Dak Kopec, an associate professor at the University of Nevada, Las Vegas. In a waiting room they would act as “contagion bubbles” that trap contaminants.
appointments. Besides, the hospital and clinic may not have the kind of spacious parking lots that facilities in car-oriented Los Angeles have. Cooper envisions hospitals and medical practices in places like New York using apps to inform patients about schedules and when to hop on the subway to get to an appointment on time with little, if any, waiting. (Of course, that presumes that the subway is reliable — and it isn’t.)

Coastal Medical, a 20-practice group headquartered in Providence, Rhode Island, is also using the cellphone lot model. Patients text or call from the parking lot. And doors are propped open, so patients don’t need to touch doorknobs during their visits, says Sarah Thompson, Pharm.D., MBA, vice president of operations and pharmacy. Coastal Medical sends out email alerts before telehealth or in-person appointments to prompt patients to sign the Health Insurance Portability and Accountability Act (HIPAA) privacy notice electronically and confirm current medications, allergies and insurance.

At the start of the COVID-19 pandemic, a majority of Coastal Medical’s patients received telehealth-based care. Now 70% of the group’s patients are using telehealth, says Thompson, who questions the purpose of patient waiting rooms in the future. She says that many of Coastal Medical’s patients feel an even closer relationship to the staff because staff are encouraging patients to keep in touch about what they’re experiencing. For example, many of the group’s patients are unemployed or furloughed and dealing with food and housing insecurity. Staff are also calling the medical group’s most vulnerable patients, says Thompson.

PODS AND BOOTHS

Dak Kopec, Ph.D., an environmental psychologist and an associate professor at University of Nevada, Las Vegas, agrees that asking patients to wait in their cars before appointments is a good short-term solution during the pandemic, but he doesn’t see it as a long-term answer.

The new waiting room will be quite different from its pre-COVID counterpart. What’s not going to work in waiting rooms, however, are the plexiglass shields now being used in stores that separate cashiers and shoppers, says Kopec. In a waiting room they would act as “contagion bubbles” that trap contaminants, he says.

The safer version of the waiting room will mean reorganizing spaces and fixing ventilation systems, says Kopec. Instead of chairs (the longer the wait, the more uncomfortable they become), he envisions “pods,” which would effectively be small rooms within the larger waiting room. Another possibility is structures similar to restaurant booths but with higher walls. The walls should be at least 7 feet high, since many people are at least 6 feet tall. A physical barrier of that height will prevent virus transmission between the patient and someone who coughs nearby and also provide privacy.

Costs could be problematic; segmenting a waiting room into pods and booths would be expensive, Kopec says.

A less costly alternative: waiting areas that are similar to the bays found in pre-operative and emergency departments with plastic curtains separating patients.

Placing tall walls or curtains between pods, booths or bays is important because viruses are heavier than air, explains Kopec. When the viruses leave the patient’s nose or mouth, they drift down. Hospital executives should also consider increasing the number of ventilation intake ducts, which will limit the pull of contaminated air into noncontaminated zones, says Kopec (see box on next page.)

Cooper at BDO agrees that there will be a return to the waiting room inside the hospital or practice, but he says that
New ways, new places for healthcare’s waiting room

Industry Analysis

patients will no longer tolerate congested waiting areas that could foster transmission or, at the very least, make them feel anxious. Brighter, “less cozy” spaces will become the norm, predicts Deb Sheehan, a managing director at BDO. Carpet and fabrics that are difficult to clean may be removed, she says, and ambient lighting will be brighter to make patients feel that the space is cleaner.

Cooper says that emergency situations and the emergency department present a different set of issues. He advises deploying a nurse practitioner at the emergency department entrance to do triage. For some patients with relatively minor ailments, the goal is “treat and street,” which may mean giving the patient a prescription and sending them home with instructions for follow-up care. It’s important to keep those patients out of the interior of the hospital where there’s a greater likelihood of coming into contact with COVID-19, says Cooper.

MAJOR INVESTMENT NEEDED

Dreaming up waiting room spaces is one thing; finding the money to do so is another. Sheehan says healthcare executives will need to redesign waiting areas to lure back patients. But most providers have seen a steep drop in revenue, even if the blow has been softened by federal government emergency funds. According to analysis done by the Advisory Board, elective procedures, which were halted this spring, make up about half of the revenue for a typical hospital. It’s also important to hospitals and medical practices to get patients in for preventive care. Breast, colon and cervical cancer screenings dropped by 86% to 94% in the early days of the pandemic, according to the Epic Health Research Network, a research arm of the electronic health record company. Those screenings were below normal volume in mid-June, said the Epic researchers. According to their tally, 285,000 breast cancer screenings were “missed” between March 15 and June 16, along with 95,000 colon cancer screenings and 40,000 cervical cancer screenings.

How soon will provider organizations be switching over to these new waiting rooms? Although none of the experts provided a precise timeline, we’re most likely looking at months, rather than years.

Aine Cryts is a healthcare writer based in the Boston area.

HVAC TO THE RESCUE?

In an article published in early July on its website, McKinsey & Company, a global management consulting firm, described four ways that heating, ventilation and air-conditioning (HVAC) systems could be engineered to prevent COVID-19 transmission.

Filtration. Air is forced through a fiber-based material or a membrane. The efficacy varies and depends on the type of filter.

Irradiation. Electromagnetic radiation — often ultraviolet-C light — is used to kill pathogens. However, this method can’t be used in occupied spaces because the light can prove harmful to skin and eyes.

Thermal. High-intensity, targeted heating can be a good fit in stand-alone units or through ventilation systems.

Ionized purifiers and ozone generators. Ionized purifiers deliver a negative charge to purify the air. Ozone generators use an electric charge to generate ozone with the same desired result.

The article also highlights the concept of laminar vertical airflow, which moves air in layers at the same speed and in a straight path. This airflow method, which may help prevent the airborne transmission of the new coronavirus, is currently in use in clean rooms and operating rooms to reduce contamination by directing air from the ceiling to the floor.
Is the handshake a thing of the past?

Because COVID-19 has put the gesture in a different light, healthcare executives are coming up with other ways to greet people. BY AINE CRYTS

Our social lives are now fraught with challenges because of COVID-19 and social distancing. Even simple gestures and mores need to be navigated. The perfunctory hug — and especially the handshake — seem like relics of the past, invitations to transmission and infection rather than signals of goodwill or a deal struck.

So what will fill the void, particularly in business settings?

The elbow bump, when each person bumps the other’s elbow, may enter the mainstream as a friendly gesture, say healthcare executives. The toe tap or foot shake? Umm, maybe not in a business setting. And there’s the shaka symbol, which more people would recognize — the three middle fingers curled over with the thumb and pinky extended — than know its name. The gesture is better known as “hang loose,” “right on” or “take it easy” and was associated with Hawaii and surfer circles before people in the mainstream started to use it ironically. The knuckles facing outward to show enthusiasm are optional.

Embracing these or other symbolic greeting gestures will require a culture change, says Kevin Ronneberg, M.D., vice president and medical director of health initiatives at HealthPartners, a not-for-profit healthcare organization in Minnesota. Letting go of the handshake will be hard for many people. Ronneberg, a member of the Managed Healthcare Executive editorial advisory board, said his grandfather instilled in him the need for a “firm handshake ... where you look people in the eye.”

Peter Coelho, M.D, a physician executive at St. Louise Regional Hospital in Northern California, says he “kind of cringed” when someone tried to hug him recently. But he understands the need to hug. “There’s been a fracture. We feel that in all of our society,” says Coelho.

What follows is some advice from healthcare executives on alternatives to the handshake and strategies for building and strengthening bonds with colleagues and patients.

ESTABLISHING A HUMAN CONNECTION

Ronneberg says it’s not about the handshake or another physical gesture. Instead, he’s focused on the message he wants to convey and on meaningful ways to connect with colleagues and patients. Unless they’re doing a physical exam, doctors aren’t touching patients these days, but they can still greet patients with joy — or express condolences — through words, says Ronneberg. Emotional intelligence helps with this, as does using words to articulate what you’re feeling and the importance of the connection you’re making. This strategy also works with colleagues, he says. For example, a colleague can feel validated when a team member acknowledges that they’re having a bad day.

Joan Budden, president and CEO at Priority Health, a non-profit health insurance provider in Grand Rapids, Michigan, jokes that some of Priority Health’s employees are thrilled that the payer has deemed itself a “no hugging” workplace.

Budden has four more suggestions for alternatives to the handshake:
The peace sign. Is the V-shaped gesture that was popular in the ‘60s and ‘70s about to make a comeback because of the COVID-19 pandemic? Baby boomers, however, may be wary about dating themselves and inducing millennial eye rolls.

The namaste. Like the shaka symbol, many more people would recognize namaste (pronounced NAH-muh-stay) than know its name. It involves bringing the palms of the hands together with the fingers pointing up and bowing slightly at the waist. “Namaste” is a Sanskrit word that means “I bow to you,” according to the Merriam-Webster dictionary.

The “hi” hand. This is very close to a wave hello. The hand is raised up with the palm out. The open palm is an ancient display of honesty, according to Business Insider, the business news website.

The awkward turtle hand gesture. The gesture is formed by putting one hand on top of the other with the fingers pointed away from body and wiggling the thumbs. Not exactly a greeting, it’s used to signal an awkward moment — in a somewhat awkward way.

Budden is partial to the namaste, thanks to her yoga class. “It means the light in me recognizes the light in you. That ‘I hear you. I was present,’” she says. The namaste can also be a farewell gesture that expresses trust and sincerity.

One not-minor problem with these gestures is that they are not universally understood. The senders may know what they mean, but if those on the receiving end don’t, the purpose of the greeting is undercut, especially if the two people don’t know each other. That’s why it will continue to be important to be present with colleagues and pay attention to physical interactions, says Budden.

MAKE ‘EM LAUGH
Leonard Kalman, M.D., executive deputy director and chief medical officer at Miami Cancer Institute, plans to continue to tell stories and inject humor into work meetings and during patient interactions. It allows people to relax while still respecting physical distancing, he explains.

But the lack of human touch when greeting patients and colleagues isn’t entirely comfortable for him, he says. “In my Jewish background, we’re big handshakers, huggers and kissers. It’s just part of the typical greeting, even with strangers.”

As a member of Miami Cancer Institute’s leadership team, Kalman has continued to physically go to the office during the pandemic. He and his physician-colleagues have embraced elbow bumps. His advice? “Turn your head away. There’s not as much risk (of transmitting the virus).”

WHITHER THE SIDE HUG
Coelho knows he won’t be using the side hug — shoulder to shoulder, facing forward — to connect with colleagues or patients in healthcare settings. Coelho says the side hug is appropriate when he meets his wife’s friends because he wants to respect their space, but it doesn’t feel right at work. Kalman agrees: “There’s no way to do a side hug while maintaining six-feet distance, he observes.

Budden won’t even go there. And she says that the traditional handshake now “seems kind of gross.” The handshake was safely appropriate before the COVID-19 outbreak, even though in some situations it seemed formal and too businesslike. But politicians “pressed the flesh” to connect voters, and American businesspeople shook hands as meetings started and sometimes when they ended.

Now, says Budden, she can’t stop thinking about where that other person’s hand has been.

HIPPER THAN A HANDSHAKE
The fist bump, which was popularized by pro athletes, doesn’t respect social distancing, but it is a good deal less “germy” than the handshake because the contact is brief.

A group of West Virginia University surgeons found that handshakes expose more than three times as much skin surface area as fist bumps; in addition, contact lasts 2.7 times longer with handshakes. And an infectious disease expert told The Atlantic that fist bumps can help prevent the spread of diseases such as methicillin-resistant Staphylococcus aureus, which can result in bloodstream infections, pneumonia or surgical site infections in healthcare settings, according to the CDC. He also observed that fist bumps have “the advantage of being kind of cool ... Perhaps our patients will appreciate our attention not only to their health but also to hipness.”

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A bout a month before COVID-19 began sweeping across the country, the results of an important study of a program — designed to address the needs of patients who are high utilizers of the healthcare system — were published in the New England Journal of Medicine. Sometimes called frequent fliers, these high utilizers tend to have multiple chronic conditions, make frequent visits to the emergency department and get admitted to the hospital often. They constitute about 5% of patients but account for about 50% of total costs, according to the federal Agency for Healthcare Research and Quality. “Hot spotting” programs, which would find ways to intervene before the high utilizers’ healthcare problems became so regular, serious and expensive, hold a lot of appeal and make common sense.

The NEJM study was supported by the Abdul Latif Jameel Poverty Action Lab (J-PAL), a research organization at the Massachusetts Institute of Technology whose founders shared the Nobel Memorial Prize in Economic Sciences in 2019. J-PAL has pioneered the use of randomized controlled trials (RCTs) to test the effectiveness of health, economic and social programs; its findings have upended prevailing beliefs more than once. The results from this particular study showed that a hot spotting program in Camden, New Jersey, that had been praised by Atul Gawande, M.D., among others, did not reduce hospital readmissions. Although hospital readmissions were 40% lower among the patients in the program, the decline was nearly the same among patients in the control group.

When the results were published in the Jan. 9, 2020, issue of the prestigious medical journal, Kathleen Noonan, CEO of the Camden Coalition of Healthcare Providers, the group running the program, told The New York Times, “We’re disappointed by the results.” Noonan added that treating such patients with effectiveness “is very, very hard work.”

Now, more than a half a year later, Camden Coalition officials say they have made adjustments to their program as a result of the RCT. “The Camden Coalition adapted its care intervention throughout the RCT and continues to do so based on what we learned since then,” Noonan says. “We found early on that we need to focus on cultivating deeper partnerships with social service organizations and launching programs that look beyond healthcare to get at the root causes of poor health outcomes.”

Since 2003, when Jeffrey Brenner, M.D., founded the coalition, the staff has recognized that these patients need primary care, social services, housing, food and, in some cases, a lawyer. “During the course of the RCT, we started programs in response to the overwhelming need we saw on the ground for things like housing and legal support,” says Noonan, pointing to the 7-Day Pledge, a citywide program that aims to get patients a primary care appointment within seven days after they have been discharged.

Noonan summarized what coalition leaders and staff have learned about patients with high utilization patterns:

- Extreme hospital and emergency room utilization is driven by the complexity of the healthcare system and the inability of most care systems to manage this complexity.
- Patients who need complex care are outliers in the health system, “so we need to build new care models capable of providing integrated care.”
- Care models need to be tailored to deliver trauma-informed and evidence-based services.
A Comprehensive Approach to Long-Term Narcolepsy Management Is Important for Patients During Their Journey1-3

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

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


For more information, contact your Jazz Account Manager or visit NarcolepsyLink.com.

*Based on a retrospective analysis of 5 years (2006-2010) of US medical claims data from the Truven Health Analytics MarketScan® Research Databases to evaluate medical comorbidity patterns, healthcare utilization patterns, productivity, and associated costs in adults diagnosed with narcolepsy (identified by ICD-9 narcolepsy diagnosis codes) compared with controls without narcolepsy matched on age, gender, geographical region, and payer.4,7
Care models must address the social determinants of health such as housing, which is a critical component of the coalition’s work.

Implementing these solutions is difficult in a healthcare system built to provide episodic care in which emergency rooms or urgent care centers may do little more than “treat and street.” Instead, almost all these patients need seamlessly integrated care in which anyone with high needs can get treatment tailored to his or her specific health and social-service needs. Getting funding for this care is a barrier to developing systems for these patients because it costs more than usual care.

Other challenges loom, ones that are beyond the easy reach of the healthcare system, Noonan says. “We must acknowledge how the issues of racism, poverty and the disinvestment in many urban areas underlie our patients’ challenges,” she says. “Without major financial and political investments in addressing those issues, any intervention will have limited impact.”

Despite these hurdles, Noonan says the coalition will continue to apply lessons learned from the RCT. “Our next steps are to continue to adapt and test programs that aim to reduce utilization of the health system (and) also to achieve our broader goals concerning quality of life for these patients, self-advocacy and other patient-identified goals.”

It’s clear that there is still so much to learn,” she notes. “We will, as we did all along, look to the data for additional insights and listen to our community and front-line staff in order to evolve our programs.”

BRENNER IS RETURNING TO PRIMARY CARE

In February 2017, UnitedHealthcare hired Jeffrey Brenner, M.D., the founder and former executive director of the Camden Coalition of Healthcare Providers, to lead a new unit improving care for UnitedHealthcare’s neediest members.

In his role as a senior vice president at UnitedHealth Group, he was responsible for introducing new models of care to the physicians and hospitals in the UnitedHealthcare’s network.

Now, after three-plus years introducing innovative models of care for the nation’s largest health insurer, Brenner will return to his roots as a family physician. In the coming months, he plans to open a primary care clinic in southern New Jersey with Kathleen Stillo, MBA, a colleague who has worked with Brenner at Camden Coalition and UnitedHealth, where she was president and chief operating officer for clinical redesign.

“I’m going to do a primary care startup,” he said in an interview with Managed Healthcare Executive. “I’m a family doc, and my true love has always been primary care.” He said he was looking for office space in southern New Jersey.

Over the course of his career, Brenner has seen how the healthcare system has failed many of the nation’s most vulnerable patients. Seeking to improve care for those who are considered high utilizers of the healthcare system, he founded the Camden Coalition in 2003. High users of healthcare constitute about 5% of all patients but account for 50% of all spending.

At the Camden Coalition, he pioneered new methods to provide what these patients need: timely and regular primary care, social services, housing, and food. He was awarded a MacArthur “Genius” Grant in 2013, and his work inspired the current attention on the social determinants of health.

His work at UnitedHealth has involved starting programs in more than a dozen cities to provide housing and other services for the insurer’s neediest members.

More recently, Brenner and Stillo spent three months running a “pandemic hotel” in Secaucus, New Jersey, for patients with COVID-19. The facility kept patients temporarily isolated from their families in an effort to stop transmission of the SARS-CoV-2 virus that causes COVID-19.

“In that setting, it was really nice to be back close to front-line care again,” Brenner said.

Joseph Burns is an independent journalist in Massachusetts who writes about healthcare.