IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS

- EYLEA is contraindicated in patients with ocular or periocular 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.

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777 Old Saw Mill River Road, Tarrytown, NY 10591
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.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® (aflibercept) 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).

Injection site hemorrhage 1% 2% 2% 2%
Intraocular inflammation 2% 3% 3% 4%
Lacrimation increased 3% 1% 4% 2%
monthly 2 mg dose in 218 patients following central retinal vein occlusion (CRVO) in 2 clinical studies (COPERNICUS and GALILEO)
Corneal edema 1% 1% 1% 1%
Retinal pigment epithelium tear 2% 1% 2% 2%
Foreign body sensation in eyes 3% 4% 4% 4%
Injection site pain 3% 3% 3% 4%
Detachment of the retinal pigment epithelium 3% 3% 5% 5%
Corneal epithelium defect 4% 5% 5% 6%
Vitreous floaters 6% 7% 8% 10%
Cataract 7% 7% 13% 10%
Eye pain 9% 9% 10% 10%

6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

• Hypersensitivity (see Contraindications (4.1))
• Endophthalmitis and retinal detachments (see Warnings and Precautions (5.5))
• Increase in intraocular pressure (see Warnings and Precautions (5.2))

6.1 Clinical Trials Experience

The clinical studies were conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in other clinical trials of the same drug and may not reflect the rates observed in clinical practice. The rates of adverse reactions observed in 218 patients treated with EYLEA compared with 2% (6 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the field, as expected.

6.2 Immunogenicity

In clinical trials, approximately 1% of patients who received EYLEA developed antibodies to EYLEA (≥0.1 mg per kg).

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

Table 4: Most Common Adverse Reactions (≥1%) in RVO Studies

EYELA (anaberpant) Injection

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

Table 6: Most Common Adverse Reactions (≥1%) in DME Studies

To date, the high incidence of adverse events observed in the wet AMD studies is consistent with the high risk of retinal detachment associated with the disease.
In Memoriam

Michael J. Hennessy Sr., 1960-2021

Mike Hennessy Sr., the beloved chairman and founder of MJH Life Sciences® and an innovative leader in medical communications, died in November 2021.

Through acquisitions and organic growth, Hennessy built MJH Life Sciences® into the largest independently owned medical communications company in North America. He was also deeply committed to improving the lives of cancer patients, active in state and national politics and, above all, devoted to his family.

Hennessy started his career in medical publishing as a sales trainee. He launched Multimedia Healthcare in 1993 and built a portfolio of award-winning clinical journals. In 2001, Multimedia Healthcare was acquired at about the same time that Hennessy was pioneering a new approach to print and digital publishing with Intellisphere®, which is now part of MJH Life Sciences®.

Hennessy added many companies and capabilities to MJH Life Sciences® through a series of strategic acquisitions. In 2004, he acquired Healthcare Research Analytics and in 2005, ArcMesa Educators. Subsequent acquisitions included Pharmacy Times® and The American Journal of Managed Care®; Physicians’ Education Resource®, LLC, PER®, a continuing medical education company; and, in 2019, the healthcare and industry sciences divisions of UBM Medica. That acquisition almost doubled the size of the company, and elevated it to being made the largest independently owned medical communications company in North America.

Hennessy also worked tirelessly on behalf of patients with cancer. As a complement to the company’s OncLive® platform, he developed the Giants of Cancer Care® awards. He acquired the CURE Media Group in 2014, which was followed by the purchase of the Chemotherapy Foundation Symposium.

In 2019, Hennessy became chairman of MJH Life Sciences® and named his son, Mike Hennessy Jr., to assume the leadership role of the organization. Under Mike Jr.’s leadership, the company has enhanced its global potential by entering into a long-term partnership with BDT Capital Partners in November 2021.

Hennessy’s counsel and insight were sought by many organizations, including his alma mater, Rider University, where he served on the board of trustees and was elected to the executive committee.

His true passion was his relationship with his wife, Patrice “Patti” Hennessy. After they met in college, Hennessy devoted his life to Patti and his family, raising four wonderful children: Shannon, Ashley, Mike Jr. and Chris. Hennessy was Patti’s rock as she bravely battled cancer for almost 10 years until her death in January 2020. Hennessy recently honored Patti by making a donation to Rider University. The Mike & Patti Hennessy Science and Technology Center is scheduled for completion this year.

Hennessy’s legacy and “family first” mantra will live on through his children, their spouses and his 10 grandchildren. He will be greatly missed by his family, friends and his MJH Life Sciences® family.
Francois de Brantes, M.S., MBA, is senior vice president of commercial business development at Signify Health.

Otis Brawley, M.D., is the Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University and former chief medical and scientific officer of the American Cancer Society.

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

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

David Calabrese, RPh, M.H.P., is market president, Health Plans/PBMs at OptumRx, a pharmacy benefits firm that provides services for more than 65 million lives nationally.

Rodrigo Cerdá, M.D., M.P.H., is vice president of clinical care transformation at Independence Blue Cross in Philadelphia.

Douglas L. Chaet, FACHE, is president of Value Evolutions and the founder and chairman of the American Association of Integrated Healthcare Delivery Systems.

Perry Cohen, Pharm.D., is CEO of The Pharmacy Group and the TPG family of companies, which provides services to associations, healthcare and information technology organizations, payers and pharmaceutical companies.

Darnell Dent is principal of Dent Advisory Services, LLC, a management consulting practice focused on helping leadership improve organizational effectiveness and overall performance. He most recently served as president and CEO of a managed care organization.

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

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

Eric C. Hunter, MBA, is the president and CEO of CareOregon, a nonprofit health plan based in Portland, Oregon.

Keely Macmillan, M.S., is senior vice president of policy & solutions management at Archway Health, a value-based care solutions company in Boston.

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

Ateev Mehrotra, M.D., M.P.H., is an associate professor of health care policy at Harvard Medical School and a hospitalist at Beth Israel Deaconess Medical Center in Boston.

Margaret A. Murray, M.P.A., is the founding CEO of the Association for Community Affiliated Plans, which represents 54 nonprofit safety net health plans in 26 states.

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

Marc Samuels, J.D., M.P.H., is the CEO of ADVI, a strategic advisory services life sciences firm in Washington, D.C.

William Shrank, M.D., is Humana’s senior vice president and chief medical officer. In this role, he is responsible for leading and implementing the company’s integrated care delivery strategy. This strategy emphasizes a consumer-friendly, evidence-based, technology-enabled approach to personalized health improvement for the company’s more than 16 million Humana health plan members.

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LOOKING AHEAD TO 2022

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6 In Brief
CMS has started to experiment with a value-based version of Medicare Advantage (MA) that allows plans to tweak their offerings in various ways to see whether they might improve outcomes. They can, for example, design benefits to target people with chronic conditions or in ways that take into account socioeconomic factors.

One of those possible value-based offerings is hospice benefits, which have traditionally fallen outside of Medicare Advantage. This year, 13 MA organizations are offering hospice benefits.

“Carving” hospice benefits into MA plan offerings could have some benefits, as Claire K. Ankuda, M.D., M.P.H.; R. Sean Morrison, M.D.; and Melissa D. Aldridge, Ph.D., discussed in an opinion piece published in November in *JAMA*. Inclusion of hospice benefits could knit together care and improve the coordination that is so often lacking in American healthcare, noted the trio from Icahn School of Medicine at Mount Sinai in New York. And MA plans could be held accountable for both the quality and the cost of hospice care.

But they also had some qualms. Ankuda and Morrison were co-investigators (along with three other investigators) of a study that surveyed family and friends of people in MA plans about the quality of end-of-life care. The results, which were published in *JAMA Network Open* in 2020, showed that family and friends of beneficiaries in MA plans were more likely to report that care was “not excellent” and that they were not kept informed than family and friends of beneficiaries in traditional Medicare.

The popularity of MA has surged, but research findings have shown that older beneficiaries with more medical issues than younger ones are more likely to leave MA plans.

In the *JAMA* opinion piece, Ankuda, Morrison and Aldridge discuss how some for-profit hospice companies have skimmed on care to improve their margins and how there’s the potential for that happening in the carve-in MA plans. They hold out rigorous regulation and quality measurement as a way to counteract tendencies in that direction.
U.S. healthcare is the most expensive healthcare in the world. Many of the policies and programs designed to rein in those costs have been predicated on the idea that information about quality and price would make Americans more discerning shoppers of healthcare—and with that shopping would come some market discipline. In November, the Commonwealth Fund published a report that provided an overview of this 40-year effort to infuse "consumerism" into American healthcare.

The results have not been very encouraging, according to the report. Take high-deductible plans. With "skin in the game," people were supposed to have an incentive to spend healthcare dollars wisely. Instead, says the Commonwealth Fund report, high-deductible plans have led people to "indiscriminately limit their use of care, including both high-value and low-value services."

Private groups and the government have produced quality report cards and ratings, but only a relatively small fraction of patients use them. The same is true of pricing information, although the new price transparency rules for health plans that go into effect in July may finally help bring about some price consciousness.

Has healthcare consumerism had any successes? The Commonwealth Fund report points to benefit designs that have linked cost sharing to value, thereby giving people a clear incentive to pick the higher-value drug or healthcare service. Tiered prescription drug formularies led to lower use of brand-name medications to lower spending, the report notes, although an unintended consequence may be less adherence (and there are issues with how formularies are shaped by rebates and other financial considerations).

The report hat tips value-based insurance design that lowers or even eliminates co-pays for high-value drugs or services. Turning Americans into value-seeking, price-watching shoppers for healthcare remains an unfinished, patchy project at best. Success, says the Commonwealth Fund report, will require integrating price data, quality information and financial incentives so people can look for and select lower-cost, higher-quality providers and care. But as the past 40 years have shown, words are more easily said than deeds are done.
This past year saw many new scientific advances reach patients. From novel vaccines and therapies to prevent and treat COVID-19 to targeted therapies for what was once considered an “undruggable” cancer, drug approvals in 2021 highlighted breakthrough science. Even more novel therapies are expected to come on the market in 2022. Oncology and rare diseases are areas in which a large number of drugs have been approved, and that pattern is likely to continue in the coming year.

One notable breakthrough in 2021 was Amgen’s Lumakras (sotorasib) to treat patients with non-small cell lung cancer (NSCLC) who have a KRAS G12C mutation. The drug received an accelerated approval in May 2021 based on the results of a study with 124 patients who had received at least one prior therapy. Lumakras is the first treatment for tumors with cells with a KRAS mutation, a target that had been considered resistant to drug therapy. “That was a big leap forward,” says Maria Whitman, global head of pharmaceutical and biotech practice at ZS, an analytics and strategy consulting firm headquartered in Evanston, Illinois. “KRAS has also been a target we’ve known about for years, and there have been many attempts to develop a target therapy. This is exciting. But this underscores for me that we still have a long way to go in the understanding of these types of targeted therapies.”

Another possible therapy for NSCLC tumors with a KRAS G12C mutation is adagrasib, which developer Mirati Therapeutics expects to be approved in 2022. The San Diego-based company began a submission to the FDA for adagrasib in November 2021 under the agency’s Real-Time Oncology Review Pilot Program. Results of a phase 2 trial with 45 evaluable patients showed an investigator-assessed response rate of 22% and a disease control rate of 87%; the median duration of response was 4.2 months.

Lessons from the pandemic
Whitman said vaccine and drug development that harnesses messenger mRNA will stay on the cutting edge this year. The development of mRNA vaccines for COVID-19 has brought attention to this innovative technology. In oncology, mRNA is being researched for use in the development of cancer vaccines, which would activate specific immune T cells to seek out and kill cancer cells.

Before the pandemic, both Moderna and BioNTech, developers of COVID-19 vaccines, were researching mRNAs application in harnessing the immune system to address cancer. BioNTech has a portfolio of oncology therapies in the pipeline that are taking several research avenues. The most advanced combines mRNA technology with the company’s lipoplex formulation, which embeds the mRNA in a type of molecule called a lipid. Other BioNTech therapies in development include BNT111, which is in a phase 2 trial as a monotherapy and in combination with Regeneron-Sanoﬁ ’s Libtayo (cemiplimab) to treat late-stage melanoma; BNT112, which is in an early-phase trial as a monotherapy and in combination with Libtayo in prostate cancer; and BNT113, which is in a phase 2 trial in combination with Merck’s Keytruda (pembrolizumab) for patients with head and neck squamous cell carcinoma.

BioNTech also has an oncology research program with Genentech to develop an individual neoantigen immunotherapy, which is in a phase 2 trial to treat patients with colorectal cancer. Moderna is researching mRNA-4157, which is in a phase 2 trial in
The pipeline is full and brimming with promise. Hat tip to science.

Drugs In The Pipeline

combination with Keytruda to treat patients with melanoma. Moderna is also conducting early research into using mRNA technology to develop treatments for cystic fibrosis and rare diseases.

“We’re only scratching the surface of what this technology can and should be,” Whitman says. “In the next few years, we’re going to see therapeutic vaccines, we’re going to see prophylactic vaccines, we’re going to see therapeutics in other areas of infection and oncology and respiratory.”

“The mRNA COVID-19 vaccines have laid the groundwork for these possibilities,” she says. “It also highlights the challenges that we learned about in terms of supply chain stability and logistics, so we’ll have to continue to advance our global infrastructure to support that.”

Jody Hessen, a clinical account executive at RxBenefits (formerly Confidio), says another important oncology approval in 2021 was Cosela (trilaciclib), which was approved in March 2021 to mitigate chemotherapy-induced bone marrow suppression, specifically in small cell lung cancer. Bone marrow suppression can lead to severe infections and is a dose-limiting factor for many chemotherapy drugs. Although it was developed by G1 Therapeutics, a Research Triangle Park, North Carolina, biotech company, Cosela is co-promoted in the United States by Boehringer Ingelheim. In October, G1 released data that consisted of pooled results from three clinical studies. This analysis found that patients who received the drug prior to each chemotherapy treatment had lower use of supportive care therapies than patients who received the placebo. Cosela reduced the occurrence of severe neutropenia, with 11.4% of patients receiving the agent versus 52.9% of patients in the placebo group experiencing neutropenia.

“Although the FDA labeling specifies myelosuppression due to treatment for small cell lung cancer, it is reasonable to assume that it will be used off-label for many different kinds of malignancies, particularly those normally treated with the same myelosuppressive drugs as small cell lung cancer,” Hessen says.

Gene therapy potential

Many experts, including Whitman and Hessen, believe gene and cell therapies will likely play a major role in treatment in the future. The question is how major and how soon into the future. Three gene therapies have been approved since 2017: Luxturna (voretigene neparvovec-rzyl), to treat patients with an inherited form of blindness; Zolgensma (onasemnogene abeparvovec-xioi), to treat children with spinal muscular atrophy; and Kymriah (tisagenlecleucel), to treat patients with acute lymphoblastic leukemia and B-cell lymphoma.

“While the gene therapy approvals are not new this year, this is a milestone of a category that has challenged us commercially and logistically. These one-time therapies are life-changing, but we’ve been challenged with the payment models for these therapeutics because of the burden on the system,” Whitman says.

Although these therapies have promise in terms of having good response rates with a single infusion, as a class, they present certain challenges in the areas of manufacturing and administration, Hessen says. First, the process of preparing doses is both time-consuming and expensive. Manufacturers have been working to develop CAR-T cell and other gene therapy products that use cells from healthy donors, which would cut down on production time; however, recent safety issues have led the FDA to halt all testing on those therapies.

“In theory, these products should provide a better balance between effectiveness and toxicity than chemotherapy, due to the fact that they target tumor cells relatively narrowly,” Hessen says.

The FDA and the National Institutes of Health (NIH) recently gave this research in the area a big lift to help address some of these issues. In October 2021, the FDA, NIH and 15 private organizations, including 10 pharmaceutical companies, launched the Bespoke Gene Therapy Consortium, part of the Accelerating Medicines Partnership program, to optimize the development of gene therapy for rare diseases. This is a $76 million effort to improve the development of viral vectors and manufacturing and to support four to six clinical trials.

Additional gene therapies may be approved in the next few years, according to Nicole Kjesbo, Pharm.D., director of pipeline at Prime Therapeutics, a PBM headquartered in the suburban Twin Cities that serves 23 Blues plans. One of the leading candidates is BioMarin’s Roctavian (valoctocogene roxaparvovec). The company plans to resubmit its application to the FDA with two years of follow-up safety and efficacy data from a phase 3 trial in the second quarter of this year. In August 2020, the FDA had sent BioMarin a complete response letter for Roctavian requesting such
information. In Europe, BioMarin’s application is under review and a decision is expected in the first half of 2022.

Another gene therapy that might be approved this year is bluebird bio’s betibeglogene autotemcel (beti-cel), a one-time gene therapy for patients with beta-thalassemia who require regular red blood cell transfusions. The therapy adds functional copies of a modified form of the beta-globin gene into a patient’s own hematopoietic stem cells. The company resubmitted its application for beti-cel to the FDA in September 2021, and the FDA has granted it a priority review with an action date of May 20, 2022. The European Commission approved conditional marketing authorization for beti-cel, marketed as Zynteglo, for patients 12 years and older.

Meanwhile, bluebird is developing other gene therapies, including LentiGlobin, a one-time treatment for sickle cell disease. But Lenti-Globin has followed a tortuous path. Early last year, the FDA put a clinical hold on the drug after one patient developed acute myeloid leukemia and another, myelodysplastic syndrome. The hold was lifted in June. bluebird is also investigating elivaldogene autotemcel, a one-time gene therapy for the treatment of early cerebral adrenoleukodystrophy. The European Commission approved the drug in July 2021.

“We are continuing to watch the gene therapy market closely both for the impact on the system to replace other persistent therapies and to solve for rare disease needs that haven’t been met before. We are likely to see more approvals of gene therapies for rare diseases this year,” Whitman says.

One therapy Whitman is excited about is a hemophilia gene therapy from uniQure, based in Amsterdam. In May 2021, the company announced positive results from a phase 3 clinical trial of 54 patients with severe to moderately severe hemophilia B treated with etranacogene dezaparvovec. At one year post-infusion, patients continued to have sustained increases in factor IX activity. The therapy consists of a viral vector carrying a gene cassette with the Padua variant of factor IX.

This therapy had been put on a clinical hold after one patient developed hepatocellular carcinoma, but a review by the FDA determined that it was unlikely that the gene therapy contributed to the cancer. The clinical hold was lifted in April 2021.

Denise Myshko is senior editor of Formulary Watch®, a website affiliated with Managed Healthcare Executive®.

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The American Cancer Society estimated that by the end of 2021, 1.9 million new cancer cases will have been diagnosed and 608,570 cancer deaths will have occurred in the United States.

With many people worried about going to a doctor because of COVID-19, there is concern that a lack of cancer screenings may cause these numbers to rise in the years ahead. Paul Limburg, M.D., chief medical officer for screening at Exact Sciences and a professor of medicine at Mayo Clinic College of Medicine and Science in Rochester, Minnesota, expects that a big focus this year will be identifying innovative ways to encourage screening and understanding which options will suit people’s needs.

Oncologists and cancer experts are also looking forward to treatment advances this year. Michael Zinner, M.D., chief executive officer and executive medical director of Miami Cancer Institute, part of Baptist Health South Florida, expects that the biggest development this year will be the further maturation of immunotherapy as the fourth type of treatment alongside surgery, radiation and traditional chemotherapy. Roy S. Herbst, M.D., Ph.D., agrees and is hoping for a wider application of immunotherapy. “Currently immunotherapy works really well in some cancers, but less so in others,” says Herbst, who is chief of medical oncology at Yale Cancer Center in New Haven and Smilow Cancer Hospital in North Haven, Connecticut. “I see this year bringing the opportunity to broaden the use of immunotherapy across all cancers by understanding what makes a tumor resistant and how we can combine different drugs based on what is happening in the tumor.”

Zinner also mentions a bright horizon for precision medicine — agents designed to attack tumor cells with specific mutation: “Both the academic world, in terms of drug development, and the pharmaceutical industry have focused on these as important areas for research and development — and they are also profitable for the pharmaceutical industry.”

Part and parcel of precision medicine is testing for the mutations that the medications home in on. “Timely access and reporting of molecular testing will be further streamlined to reduce the time from testing to medical decision-making and incorporating the appropriate therapeutic agent in the treatment plan,” predicts Ajeet Gajra, M.D., M.B.B.S., FACP, chief medical officer at Cardinal Health Specialty Solutions. “This applies to solid tumors including lung, breast and colon cancers as well as hematologic malignancies including AML (acute myeloid leukemia), MDS (myelodysplastic syndromes) and multiple myeloma.” Gajra believes a new generation of precision medicines will become available for clinical use soon, including agents that enhance the efficacy of immunotherapy agents.

**Cost and delivery**

One downside to the advances in oncology has been the rising cost of immunotherapy, precision medicine are coming on strong in oncology

But the future of value-based care in oncology is uncertain with no certain successor to the Oncology Care Model in sight. by KEITH LORIA
treatment and especially the drugs. “I worry that the cost of these treatments will continue to go up over the next year,” says Zinner, who is hopeful that telehealth and remote patient monitoring will yield some cost savings to offset the rise.

Herbst foresees more government-provided insurance, hospitals partnering with insurance companies and hospital-at-home programs. “These are designed to provide hospital-level care but in a home setting — which is especially important as demand increases.”

Oncology and value-based care, which is supposed to gear payment toward outcomes and not just volume, have had a rather uneasy relationship. Value-based care seems to be at a crossroads right now, observes Bruce Feinberg, D.O., vice president and chief medical officer at Cardinal Health Specialty Solutions. For more than a year, oncology groups have been expecting CMS to roll out Oncology Care First, the successor to the agency’s main oncology-focused value-based care arrangement, the Oncology Care Model. But the start of Oncology Care First was delayed because of COVID-19, and now it appears to be shelved, with a gap looming between the end of the Oncology Care Model in June 2022 and whatever may come next.

“Early detection of some of the deadliest cancers at earlier stages, when the disease can be more effectively treated, is our top priority, and we are energized by its potential to change cancer diagnosis and treatment,” Limburg says. “We expect to generate clinical validation data for our tumor-informed liquid biopsy test in the next 24 months.”

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

**Cancer trends are headed in the right direction**

For most of the 20th century, cancer death rates in the U.S. increased, largely because of the prevalence of smoking. But as smoking rates have decreased, so has cancer mortality. The peak year was in 1991 when 215 of every 100,000 people in the U.S. died from cancer.

The Annual Report to the Nation on the Status of Cancer that came out in July 2021 showed an acceleration in the declines in the death rates from lung cancer and melanoma but a slowing down of the decline in rate from colorectal cancer and female breast cancer and a leveling off the death rate from prostate cancer.

The report notes, though, that as the incidence of smoking-related cancer has declined, the incidence of several types of cancer that are related to excess body weight has increased, including cancers of the female breast, corpus uteri, pancreas, kidney and myeloma.

These overall trends are likely to continue in 2022, although the pause in regular cancer screening adds a wild card. Cancer incidence could increase because precancerous lesions went undiscovered and will be discovered as cancer.

The annual report on cancer is a joint effort by the American Cancer Society, the National Cancer Institute, the North American Association of Central Cancer Registries and the CDC.
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We changed our annual State of the Industry survey this year. In the past, most of our questions looked back at developments in the past year, and we published the results in the December issue of Managed Healthcare Executive. This year we pivoted 180 degrees and asked questions about the year ahead instead of the year gone by. Of course, it makes more sense to publish the results of a forward-looking survey in January.

We had exactly 100 respondents, although not every respondent answered every question. About one-quarter of the respondents said they worked for hospitals and healthcare systems and a similar proportion worked for physician groups. The rest were evenly divided among health plans, consulting firms and other kinds of healthcare companies.

The results presented on the following pages should provide insight into attitudes about 2022 and expectations for the coming year. When we asked people about their level of optimism about healthcare, the very pessimistic outpaced the very optimistic (9% vs. 2%) but the vast majority were in the milder middle, with 32% indicating that they were somewhat pessimistic, 29% that they were somewhat optimistic and 28% that they were in the neutral-feeling middle.
Which will be the most important issues facing American healthcare in 2022?

Consolidation of payers and providers
Labor shortages
High drug prices
Supply chain
COVID-19 vaccination rates
IT security
Healthcare disparities
Interoperability

Respondents ranked these healthcare topics on a scale of 1 to 10, with 10 being the most important. Rankings of importance were summed into a single value by assigning a value of 1 to a ranking of 1, a value of 2 to a ranking of 2, and so on, up to a value of 10 being assigned a ranking of 10. Those values were then summed to arrive at a single value for importance.

Rate your level of optimism about whether there will be notable improvements in American healthcare in 2022.

Very pessimistic Somewhat pessimistic Neutral Somewhat optimistic Very optimistic

32% 28% 29% 9% 2%
Which of these technological developments are most likely to have the biggest effect on the cost and delivery of U.S. healthcare in 2022? Pick two.

- Remote care technologies: 66%
- Precision medicine (e.g., genomic tests to guide treatment choices): 35%
- At-home hospital care: 29%
- Digital therapeutics: 22%
- At-home testing: 18%
- Artificial intelligence: 16%
- Interoperability: 13%
- Other (please specify): 1%

Which of these political and policy developments are likely to have the biggest effect on the cost and delivery of U.S. healthcare in 2022? Pick two.

- Drug price limits (e.g., caps on Part D out-of-pocket costs and penalties for price increases higher than inflation): 51%
- Expansion of Medicare benefits: 49%
- Expansion of ACA subsidies and credits: 36%
- Expanded funding for home health services: 26%
- Incentives and programs to address social determinants of health: 14%
- Incentives and programs to address health disparities: 12%
- Antitrust actions: 7%
- Other (please specify): 5%
Please pick the statements that most closely resemble your views of the efforts to address health disparities. You can pick more than one.

- They are admirable but will take a long time to demonstrate an effect: 45%
- They are long overdue: 43%
- They are a good investment into the root causes of health and illness: 36%
- They are politically motivated: 32%
- They are admirable but the chances of success are small: 17%
- They are a distraction from what healthcare organizations should be focusing on: 14%
- They are trendy and will fade with time: 9%
- No opinion on efforts to deal with disparities: 4%

Do you expect your organization to take meaningful steps this year to address health disparities in 2022?

- NO: 51%
- YES: 49%

Rate your level of confidence that the focus on health disparities will result in meaningful change in U.S. healthcare in 2022.*

- Very low: 14%
- Low: 28%
- Neutral: 40%
- High: 14%
- Very High: 3%

*Percentages for this and several other questions in the survey do not add up to 100 because of rounding.
Please rate your level of agreement with these statements about the future of the COVID-19 pandemic.

COVID-19 will become an endemic disease

- Strongly disagree: 3%
- Somewhat disagree: 7%
- Neutral: 13%
- Somewhat agree: 49%
- Strongly agree: 28%

New variants will start to circulate, but the current vaccines will protect against them

- Strongly disagree: 6%
- Somewhat disagree: 15%
- Neutral: 26%
- Somewhat agree: 44%
- Strongly agree: 8%

New variants will start to circulate, and the current vaccines won’t protect against them

- Strongly disagree: 7%
- Somewhat disagree: 30%
- Neutral: 28%
- Somewhat agree: 16%
- Strongly agree: 7%

Monoclonal antibody therapies will play an important role as pre-exposure prophylaxis

- Strongly disagree: 16%
- Somewhat disagree: 35%
- Neutral: 21%
- Somewhat agree: 14%
- Strongly agree: 15%
What are your biggest concerns about COVID-19 vaccination in 2022?

- The vaccines will be ineffective against future variants
  - Not concerned: 3%
  - Mildly concerned: 22%
  - Neutral: 28%
  - Very concerned: 7%
  - Extremely concerned: 40%

- The safety of vaccines for children
  - Not concerned: 28%
  - Mildly concerned: 19%
  - Neutral: 18%
  - Very concerned: 19%
  - Extremely concerned: 16%

- Low vaccination rates among children
  - Not concerned: 12%
  - Mildly concerned: 20%
  - Neutral: 18%
  - Very concerned: 33%
  - Extremely concerned: 17%

- Low vaccination rates among teens
  - Not concerned: 8%
  - Mildly concerned: 21%
  - Neutral: 18%
  - Very concerned: 35%
  - Extremely concerned: 20%

- Vaccine misinformation on social media
  - Not concerned: 4%
  - Mildly concerned: 9%
  - Neutral: 7%
  - Very concerned: 14%
  - Extremely concerned: 66%
Which consolidation trend is most likely to accelerate in 2022?

- Vertical integration of provider organizations (e.g., hospitals and physician groups): 40%
- Horizontal consolidation of provider organizations: 24%
- Vertical integration of payers: 13%
- Horizontal consolidation of payers: 12%
- None: 11%

Do you favor the Biden administration using antitrust law to slow down or block further consolidation among providers?

- NO: 41%
- YES: 59%

Was it a mistake for the FDA to approve Aduhelm (aducanumab)?

- NO: 46%
- YES: 54%

Has the FDA approved too many drugs through the accelerated approval process?

- NO: 74%
- YES: 26%

Should states increase regulation and oversight of PBMs in 2022?

- NO: 35%
- YES: 65%
Where would you place your organization in the shift away from fee for service to value-based care?

- Have not yet started: 27%
- Have a few cost-only initiatives started: 19%
- Have a few quality-only initiatives: 18%
- Have many cost/quality initiatives: 18%
- Most of the business is focused on value-care: 17%

By the end of 2022, what proportion of your current value-based contracts do you expect to involve downside risk for your organization or the organization you contract with?

- 0-25%: 41%
- 26%-50%: 23%
- 51%-75%: 9%
- 76%-100%: 3%
- Not applicable: 23%

Which of these value-based arrangements is most likely to be successful in improving outcomes and reducing costs in 2022?

- Pay for performance incentives: 39%
- Directing contracting between employers and provider organizations: 20%
- Bundled payments: 18%
- Global capitation: 13%
- ACOs: 10%
In the first half of 2020, the coronavirus forced the healthcare system to transform itself in dramatic ways that continue today. Those changes are likely to remain in place throughout the early part of 2022, if not through the entire year and beyond.

In interviews with Managed Healthcare Executive®, executives and experts predicted that the American healthcare system will continue to add more telehealth to the delivery system, particularly for those needing mental health and substance abuse treatment. At the end of 2021, this form of care delivery was becoming so popular that insurers were offering telehealth as a virtual-first product.

In addition, experts predicted, the healthcare system will continue to focus on the never-ending battle to rein in costs.

Rising pressure for cost control
This year and next, two forces will come into play and increase the focus on the need to control healthcare costs, predicts David Muhlestein, Ph.D., J.D., chief strategy and chief research officer for the consulting firm Leavitt Partners. One is the perilous state of the Medicare trust fund, which will be exhausted unless Congress changes how the program is paid for, the amounts paid, or some combination of the two, according to Muhlestein. The other is healthcare cost pressures on health plans and employers as the nation moves out of the acute phase of coping with the COVID-19 pandemic to what seems likely to be an endemic respiratory disease. “In 2022, cost pressures will start to come back,” Muhlestein says.

The estimates vary. Medicare’s Hospital Insurance Trust Fund is projected to be exhausted in about three to six years, Muhlestein notes: “No one is certain about when it will happen, but it’s definitely on the horizon.”

Given that the Medicare program covered about $830 billion in healthcare costs in 2020, roughly one-quarter of total U.S. healthcare expenditures, the financial health of the trust fund should be one of the most pressing topics for discussion in Washington. But politics and the midterm elections this year will likely postpone any such serious consideration of the problem till late this year or early next year, according to Muhlestein. “There has to be a conversation around how to address the Medicare trust fund,” he says, “but my guess is that the election will distract Congress for the next year or so.”

Muhlestein sees an “or else” scenario for Medicare: substantive changes in the program or else some drastic cuts in payments. “That would be incredibly disruptive for physicians, hospitals, health plans and anyone who has Medicare or Medicare Advantage or is in a managed Medicaid plan because they would all be affected by those changes,” he points out.

At about the same time, the entire U.S. healthcare system may be entering what Muhlestein sees as a post-acute COVID-19 period. Providers and payers will need to adjust and perhaps manage costs without the significant levels of funding that the federal government has invested in shoring up the health system during the height of the pandemic. Another factor may be an uptick in the use of healthcare services as people who held back from getting care start needing it, possibly when their disease is at a more serious stage.

Healthcare providers will need to be more flexible than they have been in the past, Muhlestein pre-
dicts. “For a long time, the health system has been based on building capacity around well-reimbursed procedures,” he notes. Space and resources were devoted to a single purpose. Now and in the immediate future they will need to be more nimble, reallocating room and resources from one kind to another.

“The analogy I use is a hotel ballroom, which can handle a big conference all in one room or ... provide space for a luncheon or a small wedding,” continues Mulhlestein. “Whatever it is, the space can be repurposed very quickly to fit certain needs.” If there are just a few cases of COVID-19 in a community, some rooms — indeed, whole facilities — may not be needed. But if serious cases spike, those rooms or facilities, and the doctors and other healthcare professionals needed to staff them, could be put to use quickly, he notes.

**More virtual mental health care**

The toll the pandemic has taken on people’s mental health has been well documented. Isolation has increased. The stress of unemployment has affected millions of workers who were laid off. Now labor shortages are affecting those who have stayed in their jobs. Research findings have shown that the prevalence of depression has increased. “The pandemic has elevated mental health as an area of focus for all stakeholders, but particularly for employers and all purchasers more generally,” says Michael Thompson, president and CEO of the National Alliance of Healthcare Purchaser Coalitions.

Employers want to see changes, such as greater integration of mental health across the entire spectrum of health care services, including primary care, Thompson says.

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**HEALTH INSURERS OFFERING A “VIRTUAL-FIRST” OPTION**

For many people, telehealth is an inviting option. But some insurers are offering health plans that make it the main way by which people receive primary care.

In October 2020, Priority Health, one of the largest health insurers in Michigan, announced it was offering a “virtual-first” option to some members. Starting last year, Priority Health members who signed up for one of three MyPriority Telehealth primary care provider (PCP) plans had all primary care visits conducted virtually through its provider partner, Doctor on Demand, a group of physicians and other providers who deliver all care via telehealth.

Any member needing to see a specialist in person would need a referral from their PCP. Priority Health said the new plans were designed for those who are comfortable with online interactions with providers, says Carrie Kincaid, Priority Health’s vice president of individual markets.

Following Priority Health’s lead, three other insurers announced this year that they will offer virtual-first plans in 2022. CVS-Aetna announced in August 2021 that it would partner with Teladoc Health to offer a virtual plan to employers nationwide. UnitedHealthcare and Centene Corporation have also jumped on the virtual-first bandwagon. Centene said it partnered with Teladoc Health to provide virtual care in Michigan, Mississippi, South Carolina and Texas. UnitedHealthcare offered its NavigateNOW virtual-first plans in Dallas, Houston, Minneapolis, Indianapolis, Pittsburgh and several other cities. Members who choose the NavigateNOW get around-the-clock access to care and same-day appointments and have no copayment for virtual and in-person primary care. There is also no copayment for behavioral health visits and virtual urgent care, the insurer said in a news release. Employers’ premiums for NavigateNOW plans are 15% lower than comparable health plans, UnitedHealthcare said in its press release.

In November, SCAN Health Plan, which offers Medicare Advantage plans in California, launched Welcome Health, an independent primary care medical group that will treat MA members through a combination of virtual and in-home visits.

In an interview with Managed Healthcare Executive®, Kincaid said that Priority Health introduced three virtual-first plans on the individual market in Michigan. One is a bronze plan, the other two, silver. About 5,000 people signed up for plans. Kincaid said that 60% of members who responded to a patient satisfaction survey rated their satisfaction at 4.8 out of 5 stars. “When introducing these plans, we were very focused on wanting to improve the quality of care that patients receive through the accessibility of this product,” she said. Priority Health has noted that some of the patients enrolled in virtual-first care are more engaged in their care than they were previously, she added.

“Among members with diabetes we’ve noticed that they are more engaged in their care and, as a result, they’ve been able to bring their A1C scores down significantly,” Kincaid said. “Other members have brought their weight down.”
Industry Analysis | Telehealth grows, but Medicare has woes

**Net Medicare spend to almost double**

Net Medicare spending is the government outlay minus revenue from premiums and other sources

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All figures are billions of dollars. Source: Congressional Budget Office, “The Budget and Economic Outlook: 2021 to 2031,” February 2021

Physicians, hospitals and health systems need to demonstrate with data that they are doing more to diagnose mental health issues earlier and to assess patients’ progress while in treatment, he says. But Thompson sees a bright spot in the pandemic: greater access to telehealth, especially for mental and behavioral health services. In his view, telehealth can help fill the void in underserved areas. "For too long," he says, "employers and other purchasers have tolerated unequal access to mental health services."

In a survey of 142 employers that Thompson’s organization conducted last year, almost all (92%) of the respondents said that access to care for mental health conditions and substance use disorders would be a priority over the next two years. Telehealth has become one of the main sources for providing access.

"Telemedicine and tele-behavioral health care are here to stay," says Thompson. "You can’t put that toothpaste back in the tube because it’s more convenient and safer than conventional face-to-face counseling. Also, in many ways, efficacy is higher, in part because it integrates measurement over the course of treatment into the care process." What’s more, he continues, telehealth allowed more mental health providers to deliver care than ever before, a problem policymakers had struggled to solve before the pandemic.

For health insurers, the pandemic has demonstrated the benefits of providing care via telehealth. This is shown by the rising number of health insurers that have embraced what they call virtual-first care, in which physicians and other providers meet with patients first and almost exclusively via telehealth.

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Managed Healthcare Executive.com
Amazon is poised to continue its 2022 expansion in more than just e-commerce sales. It’s about to become the largest U.S. carrier for delivery services. Yes, larger than the U.S. Postal Service, UPS and FedEx. That may sound unrelated to healthcare, but it really isn’t. That infrastructure is helping Amazon deliver their own branded PCR COVID-19 tests. It’s helping them deliver pharmaceuticals through PillPack. And it may help them become an even bigger player in the home health arena.

With Amazon, “their movement is large, but it’s also really long,” says Robin Gaster, a visiting scholar at George Washington University Institute for Public Policy and the author of “Beemoth, Amazon Rising: Power and Seduction in the Age of Amazon.” Amazon observers such as Gaster expect Amazon’s current healthcare endeavors to grow this year but don’t anticipate a big, splashy announcement for a new service or product. The moves into healthcare are likely to be more subtle, with entry into new markets for current offerings, or an expansion in capabilities.

Here are three areas to watch in 2022:

1. Amazon Care’s embrace
One of Amazon’s main healthcare moves right now is primary care. Just as Amazon built Amazon Web Services for its own data storage use and then commercialized it, the company is positioning itself to do the same thing with Amazon Care. “They build something for themselves and then sell it to others,” Gaster notes.

Amazon Care rolled out in 2019 as a service for the company’s Seattle employees, followed by an expansion to its Washington state employees in 2020. Last year Amazon extended virtual care to its employees in all 50 states. This year, employees in 20 major U.S. cities can access in-person health-care services, including home or office visits, plus telehealth.

With low reimbursement rates to providers and few procedures to bill for, primary care has long been a problematic area for American healthcare and its providers. Primary care is, in theory, a bargain, partly because preventive services can reduce the utilization of expensive acute care. But it is also hard to please the patients who want convenience and affordability. This presents an opportunity for Amazon, as the “customers” are not especially well treated in primary care, Gaster says. “It’s a place where Amazon’s focus on the customer could pay big dividends.”

In 2022, Amazon may start turning healthcare into an engagement vehicle to make employees happier while improving health outcomes and potentially shaving costs for employers. With the pilot venture and national expansion under its belt, Amazon Care signed up fitness company Precor, its first outside employer client, in May 2021. The app-based primary and urgent care was offered to a subset of Precor’s Washington state employees. The hospitality company Hilton signed on next, in November 2021. All U.S. staff members enrolled in the corporate health plan will receive this benefit in 2022, including texting services, virtual healthcare visits...
and house calls, depending on the location.

2. Remote diagnostics
Although Amazon did not try to draw a lot of attention to its entry into COVID-19 testing, the company began offering PCR tests online in 2021. “I thought it would be antigen tests, but it makes more sense for PCR, as it lays into their logistics infrastructure,” says Tom Kiesau, leader of digital health at The Chartis Group, a healthcare advisory firm. “Amazon has the logistics to easily drop the test off and pick it up again, bypassing the clinic setting, and they have the data infrastructure to quickly share the results faster than many other organizations.”

The Amazon Halo isn’t new, but it may gain capabilities in the next few years to make it more of a player. The diagnostic tool and fitness tracker caters to that relatively narrow niche of quantified-self adopters — people who enjoy monitoring their activity levels, heart rate, sleep, body fat percentage and vocal tone, which can be analyzed for signs of stress. Consumers may find some of these functions useful, notes Kiesau, but “I don’t necessarily see a direct (patient) benefit” at this point. It needs more capabilities to create good value, he says.

Those additional diagnostic capabilities might be tools to manage diabetes and heart disease, and to do it more effectively than it’s done now. “Those are the diseases that are bankrupting the health system,” says Gaster. If Amazon can find ways to significantly reduce the costs by lowering testing costs and making tracking more effective, clinicians could perhaps intervene earlier and head off hospitalizations and other kinds of expensive healthcare.

3. In the home
Alexa, Amazon’s virtual digital assistant, already has a library of advice for breastfeeding, first aid and issues including improving medication management and adherence. But this year Alexa will continue making inroads in the home setting, particularly for the older population. Amazon sees capability, if I’m a health system, I can have a virtual entry point into almost every patient home,” Kiesau says. Patients talking to their local clinicians may be more comfortable with the service. For now, Amazon is just in charge of the logistics, with the clinical expertise left to the healthcare organizations. It will be interesting to see whether Amazon moves into the care portion in the future.

Alexa Smart Properties complements Amazon Together, a subscription service allowing loved ones to remotely check on older adults or those needing monitoring. “It’s a pretty smart solution to a growing problem,” Gaster notes, with so many parents living away from their grown children. The tool allows those given access to monitor the person’s activities and potential falls, and to call for assistance when needed. It solves a problem, as “there’s an extreme shortage of nurses and people to work in home and congregate care,” Gaster says.

Amazon may move more into services and supportive care for patients with medical issues. In 2021, Penn State started offering supportive care to those with metastatic breast cancer, with Amazon Echo Show answering questions about symptoms such as pain,
fatigue, sleep and mental health issues. It shares evidence-based interventions including cognitive behavioral therapy and guided meditation. Tools like this can help extend healthcare services into the home while freeing up clinician and staff time, and still provide value to patients.

The 2021 American Rescue Plan provided additional funding for home care for seniors and those with disabilities, and Amazon Care, Intermountain Healthcare and Ascension joined forces to form a healthcare coalition called Moving Health Home to advocate for expanding home-based clinical care. Kiesau said he was surprised to see two established healthcare provider groups partner with Amazon Care. However, the complexity of deploying a hospital-at-home solution involves distributed logistics, nursing, respiratory therapy, devices, lab studies, phlebotomy and devices. “There’s so much getting moved around,” he says, and it’s hard enough for hospitals to track it in their own facilities, let alone tracking it across a metropolitan area. “Amazon is pretty good at doing that. On my phone I can see where my package is on a map and it’s telling me, based on the driver’s projection, when (it’s) going to get there.” That ability and technology ecosystem make Amazon a logical choice as a partner in a home-based care program.

**AWS and data**
In mid-2021, Amazon launched Amazon HealthLake as a general service. The company already stored data through its AWS service, but previewed this service in 2020. Amazon HealthLake gives healthcare organizations a HIPAA-compliant service for analytics and visibility of both individual and overall patient populations. “This is a place where their technology and pretty insatiable thirst for data can come into play because they can provide services potentially at the top end of the healthcare system on the data side, all the way from managing clinical trials way down to patient data,” notes Gaster. Through data, Amazon can gain or retain an edge with integration capacities helpful in providing services and acquiring data for and from partners. “In the world of machine learning and artificial intelligence, the one with the most data wins,” says Gaster.

During a preview period, several customers used Amazon HealthLake for different purposes. Rush University Medical Center used it to address health inequities in its COVID-19 response, to better understand how the organization was caring for patients with the disease. The center also extracted information from the medical records on the patients’ medications, previous conditions and diagnoses to provide more comprehensive information to providers. Cortica used the service to better track the progress of patients with autism. And CureMatch used it to help provide clinical decision support to oncologists for personalized cancer treatment options. With increased access to healthcare organizations in 2022, one can expect the use cases to expand.

**The end of Haven**
Amazon starts a lot of pilot schemes. Not all of them have taken flight. The Haven healthcare venture, which Amazon, JPMorgan Chase and Berkshire Hathaway formed, shut down in early 2021. Although some in business said Haven failed because it’s difficult to disrupt healthcare, Kiesau has a different take. “One partner (Amazon) realized it didn’t need the other two partners,” he explains. JPMorgan Chase and Berkshire Hathaway make more sense as Amazon clients, he says. “Amazon pressed the accelerator owning this space,” and using the Amazon Care infrastructure it was creating for its own employees, the company is now selling it to others. It is notable, says Kiesau, that Amazon is using a more aggressive, disruptive approach than typical employee health programs.

In Gaster’s opinion, Amazon jumped ship from the Haven partnership because the project didn’t move fast enough, not because it failed. The company expanded its rollout of Amazon Care quickly after that. “Amazon tends to repurpose things they abandon,” he says. In 2022, Amazon will likely continue building out offerings around care areas such as joint orthopedic management, pain management and sleep tracking, all with well-established implications for other health issues, Kiesau says. The company may also partner with traditional healthcare providers to bring about a more comprehensive version of in-person care. Amazon may provide the infrastructure alone, or they may take over the wellness area.

“There’s not convincing evidence that Amazon knows how to do services, but it’s absolutely coming because Amazon needs the revenues,” Gaster says. That may not all occur in 2022, but “it’s emerging slowly out of the mist.”

Deborah Abrams Kaplan is a freelance writer who covers medical and practice management topics.
Bumps in the road ahead for retail health

Walmart seems to be pulling back and opioid litigation looms.

by SUSAN LADIKA

In this on-demand society in which people want what they want, when they want it, experts are predicting consumers will continue to turn to retail clinics for their healthcare needs in the coming year.

With millions of Americans having received their COVID-19 vaccinations at retail clinics, “people are getting more familiar” with such clinics and “realize this has a real place in the care continuum,” says Neal Batra, a principal in the life sciences and healthcare practice at Deloitte Consulting. “The industry is convinced you’ll be able to (receive) some portion of your primary care not from a classic doctor’s office,” he adds.

The clinics at drugstores such as CVS, Walgreens and Walmart are a draw because of their convenience and easy access, says Joyce Yu-Chia Lee, a health sciences clinical professor at the University of California, Irvine. The goal is to “seamlessly integrate into their (consumers’) busy lives,” says Willie Hoag, co-founder of Tether Advisors, a commercial real estate advisory firm.

Mixed bag
But not everything is so rosy for retail healthcare clinic operators. They are fighting off lawsuits accusing them of responsibility for the opioid epidemic. In late November, a federal court jury in Cleveland found that CVS Health, Walgreen and Walgreens had contributed to the cause of opioid overdoses and deaths in two Ohio counties. There are also the headwinds of healthcare delivery’s migration to telehealth and in-person shopping to online. CVS announced in November it was shuttering 900 drugstores around the country over the course of three years, or roughly 1 in 10 of its 10,000 locations. “Organizations are still looking for that magic formula for what works for retail primary care,” notes Batra.

And CVS is still trying to shift from being a retailer of healthcare products and drugs to a provider of healthcare with its HealthHUB locations that offer a variety of healthcare services, such as mental health therapy, screening for chronic conditions and health classes.

During an investor’s day presentation on Dec. 9, Karen Lynch, the company’s CEO, said CVS is “transitioning what we call stores to health destinations.” In the future, Lynch said, the company’s physical locations will fall into one of three categories: primary care clinics with a “high level of clinical services,” HealthHUBs “with products and services that support everyday health and wellness” and traditional pharmacy locations. Lynch did not say how many locations would be in each category. She also painted a picture of CVS moving more fully into primary care, shifting away from what episodic care to what she called “longitudinal care.”

CVS, which acquired Aetna for $69 billion in 2018, is marketing health plans that encourage consumers to use CVS by offering...
care at its MinuteClinics with no copays.

Meanwhile, Walmart seems to be experiencing healthcare hesitancy. The giant retailer opened just 20 of the 125 clinics it had planned to open by the end of 2021, Insider reported. Walmart executives didn’t even mention retail clinics in their November earnings call. In the August call, Doug McMillon, the company’s president and CEO, said, “The work we did to build some clinics has been helpful, and I think we’ll have more clinics in the future. But the clinics aren’t the thing on its own.” He also referred to the role of telehealth, and healthcare at home and on mobile devices and the importance of directing consumers “to the place to get the right care at the right time.”

On the other hand, Walgreens seems to be forging ahead with its partnership with VillageMD. The retailer announced in October it was investing $5.2 billion in VillageMD to increase the delivery of value-based primary care. With that investment, Walgreens upped its stake in VillageMD from 30% to 63%, and VillageMD plans to hold an initial public offering next year.

With the Walgreens investment, VillageMD plans to open at least 600 Village Medical clinics at Walgreens in more than 30 markets by 2025 and 1,000 clinics by 2027. More than half are slated to be developed in medically underserved communities. Because it is expensive to build clinics, retailers have an advantage by already having brick-and-mortar locations in place, says Hoag.

People are receptive
So far, only a relatively small group of people use retail health clinics. A Morning Consult poll of 2,200 adults conducted last year found that just 8% of respondents indicated they went to a retail clinic for medical services often and 27% said they used the clinics “sometimes.” But more than 70% of the respondents said they trusted retail health clinics and 10% said they would go to the clinics “often” after the pandemic, whereas 45% said they would go there “sometimes.” Additionally, the majority of respondents said they valued the quality of care, cost of service and convenience of such clinics.

But respondents were split when asked whether the quality of services was the same quality as they would receive at a traditional doctor’s office. About one-third said it was the same, more than one-quarter said it was worse and about 30% said they didn’t know.

The pandemic has driven growth in retail clinic usage, observes Gurpreet Singh, U.S. health services leader for PwC, a consulting firm. A pre-pandemic 2019 survey by PwC’s Health Research Institute found that 30% of U.S. adults had visited a retail clinic. A September 2020 survey found that the share of respondents who visited a retail clinic had climbed to 40%, and about three-quarters said they would use a retail clinic again.

The clinics tend to provide care “especially for people who do not have a primary care physician,” such as younger people, notes Lee, the University of California, Irvine, professor. “Retail is more geared to people with less complicated conditions,” she adds.

One aspect of retail healthcare that has perhaps not received as much attention as others is the pricing. Batra notes that prices are transparent, so people know what they are going to be charged, in stark contrast to the often-opaque pricing in traditional healthcare. But he also points out some drawbacks of retail healthcare. The services are often limited. If someone needs, say, three services, they may find that only two are provided by the retail clinic. For that and other reasons, retail health is not going to replace primary care physicians, says Batra.

Hoag believes that the future of the retail clinics lies in providing preventive care — which is consistent with the vision that Lynch mapped out. With their numerous locations, retail clinics can play an important role in increasing health equity, says Singh: “Being part of the community can and should result in more activism in the community and better representation of the demographics.”

Susan Ladika is an independent journalist in Tampa, Florida.
COVID-19 will continue to cast its long shadow on U.S. healthcare in 2022. But for population health, there is that silver lining people so often look for: innovations and adoption of telehealth that started in 2020 will continue in 2022, even if the peak use of telehealth has tapered off. Providers and payers are also continuing to move “upstream” to the social determinants of health (SDOH), investing in housing, transportation and other factors that affect people’s health but are outside of traditional healthcare. Another major agenda item for population health leaders next year is efforts to address healthcare disparities. Disparities in outcomes and access are deeply rooted problems that lend themselves to a population health approach — but not to quick fixes.

Go telehealth!
Almost two years after COVID-19 forced a telehealth revolution, patients have come to expect live video interaction offerings from their health plans and providers. Telehealth — which once meant having a live video visit with a physician — has become a commodity, with hundreds of options now available to patients, says Sebastian Seiguer, J.D., MBA, CEO of emocha Health, a medication adherence company in Baltimore that is a Johns Hopkins spin-off. Simultaneously, the very definition of “telehealth” is changing, as consumers and providers alike become comfortable using a variety of digital tools such as texting, online portals and artificial intelligence (AI)-powered chatbots to give personalized healthcare advice and support.

Specifically, Jessica Sweeney-Platt, vice president of research and editorial strategy at athenahealth in Watertown, Massachusetts, expects virtual care to continue to evolve, as it expands from a reactive mode of handling sick visits to incorporate proactive, convenient, preventive care. This is particularly true for patients working with care teams to manage chronic illnesses. In tandem, wearables, which provide the ability to monitor health at home, will gain popularity. Along these lines, Nina Birnbaum, M.D., medical director of innovation acceleration at Blue Shield of California, says that more home monitoring is coming online with on-demand electrocardiograms, continuous glucose monitors and other opportunities for people to actively engage in their healthcare. These tools should help physicians better determine what diagnostic workups and treatments are needed, potentially lowering costs.

One example of telehealth saving money occurred when the Fresno County, California, Department of Public Health used emocha Health’s digital medication adherence program for one year. The department avoided about 110,000 vehicle miles while saving $10,000 in fuel and $100,000 in salaries, Seiguer says.

Another group of products are from companies looking to amplify existing models of in-home care with technology. A company called Heal is looking to bring back house calls; Papa Health provides health-care worker visits and general help at home for lonely older adults; and Ready offers in-home urgent care visits. These are just a few examples...
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of emerging categories, with some players overlapping and others defining entirely new segments, Seiguer says.

Telehealth can also enable a hesitant or time-constrained person to access care conveniently and quickly, helping to catch disease progression earlier and ultimately prevent small problems from becoming big ones, says Karen Ignagni, president and CEO of EmblemHealth in New York, New York. In addition, telehealth helps to manage chronic conditions and treatment adherence by providing simple, quick ways for people to check in with providers.

The government is beginning to recognize the benefits of telehealth and, more broadly, care that is delivered remotely and digitally. CMS provided reimbursement guidance for a new category of digital health, remote therapeutic monitoring, in early November 2021 that compensates providers for caring for patients outside of a physician’s office. Healthcare providers have not had a financial incentive to ensure that their patients understand and take their medication completely and properly. These new remote therapeutic monitoring codes provide reimbursement for the kind of support that can lead to greater adherence, Seiguer says.

2 An eye on SDOH
An emerging trend in tackling SDOH is a greater focus on analyzing barriers to care at the population level and then investing in community programs that can have the greatest impact on the most people. Sweeny-Platt says that providers and payers both have obstacles to overcome. “While provider organizations are driving these conversations — especially those who have taken on Medicare Advantage or managed Medicaid risk — they don’t always have the resources to build programs,” she observes. “Payers have also invested in these types of programs but have struggled with low adoption. This leaves a lot of opportunities for payer and provider collaboration.”

SDOH present issues that can’t be solved peripherally, say experts. “Successful organizations are those that can marry sophisticated network-level analytics in order to identify hot-spot practices with common sets of needs, with deep local knowledge of community resources and partners,” observes Sweeny-Platt. Among the biggest challenges, she adds, is determining who pays for these programs. Robert Bollinger, M.D., M.P.H., a professor of infectious diseases at the Johns Hopkins University School of Medicine and one of the inventors of the technology licensed to emocha Health, says healthcare institutions should engage in strategic public-private and nongovernmental programs (e.g., Medicaid, community/faith-based organizations) to address SDOH issues. He also says they need to push for more resources to support SDOH efforts.

3 Addressing disparities
There is a good deal of overlap between dealing with SDOH and closing healthcare disparity gaps. Bollinger says it’s important to remember that any population health effort to address SDOH must also take into account racial discrimination — in society as a whole as well as in healthcare. He listed some steps that leaders of healthcare entities can take to begin to deal with disparities:

- Prioritize the measurement and report health disparities based on race and other SDOH factors within their clinics, facilities, digital programs and among providers.
- Build meaningful partnerships with trusted community partners — churches, local politicians — to enable patients and members to play significant roles in developing solutions that are meant to address these disparities.
- Make racial equity a strategic priority for an entire organization. Many organizations are emphasizing and implementing training, cultural competency or workforce diversity initiatives. But training alone is not sufficient. “Equity needs to be more than a standing topic for every C-suite meeting, leadership meeting and program,” Bollinger says.

Christopher Dodd, M.D., chief medical officer of PopHealthCare in Franklin, Tennessee, and its home care business, Em cara Health, says that Emcara deploys home-based advanced primary care teams that include culturally aligned community health workers. “This approach enables us to build trusting relationships with underserved community members,” Dodd says. This model, along understanding the social and environmental factors affecting health, helps to prevent serious and costly health issues before they arise, he adds.

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Chronically and critically ill patients often need acute care after their stay in an intensive care or medical/surgical unit. While these medically complex patients make up a small part of overall care delivery, it is critical to identify the appropriate care setting for them in order to decrease the risk of costly rehospitalization.

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