Proton Beam Radiation
3 decades after approval, the debate about this cancer therapy continues
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A tale of two technologies

The advances in medical technology have saved untold lives and prevented incalculable suffering. The fact that we now have three vaccines against COVID-19 in the United States testifies to the value of U.S. technology and innovation. The Pfizer and Moderna vaccines are RNA vaccines, and researchers have been investigating RNA technology for vaccines and treatment for decades. It took the crisis of the COVID-19 pandemic and a massive public-private partnership to make the RNA vaccines a reality. One of the virtues of RNA vaccines is the speed at which they can be developed. Once the genetic sequence of the pathogen is identified — the sequence of the coronavirus that causes COVID-19 was made publicly available in January 2020 — researchers can pull out the segment that encodes for the antigen and, after several intermediate steps, have a piece of RNA that can be packaged up as a vaccine.

This issue of Managed Healthcare Executive includes a story about an entirely different sort of technology that has moved into American healthcare at an entirely different pace: proton beam radiation therapy, which the FDA approved more than 30 years ago. The physics of proton radiation means that it scatters less than does conventional radiation, which uses photons, commonly known as X-ray. As our story explains, proponents say that means less toxicity and possibly stronger doses of radiation. But conventional radiation has also improved with the advent of intensity-modulated radiation therapy. And although the equipment companies have made some adjustments, constructing proton beam radiation facilities is expensive, and therefore the cost of proton beam radiation therapy tends to be higher than conventional therapy. Head-to-head trials are few and far between. The result is a situation more typically seen with new advances, not technology approved three decades ago: insurers balking at the cost, patients suing for coverage and uncertainty about how the technology should best be used.

“Proton therapy is a proven treatment for cancer — there’s no doubt about it. Period,” Justin E. Bekelman, M.D., told us. Bekelman is a professor of radiation oncology at the University of Pennsylvania and the principal investigator of an important clinical trial comparing proton beam radiation with photon radiation as a treatment of breast cancer. “However,” he continued, “what remains undefined is whether it is any better than what we currently use, which is photon-based treatment and, most commonly, intensity-modulated radiation therapy. That is the debate. It is a proven treatment, but is it proven as better than what we usually do for the prevalent cancers? The answer is not yet.”

Technology is the wellspring of innovation in U.S. healthcare. It must be rewarded and celebrated. Our lives are better for it. But sometimes the truth of how it should be used and valued may emerge more slowly than we would like.
3 decades after approval, the debate about this cancer therapy continues
Mission
Managed Healthcare Executive® provides healthcare executives at health plans and provider organizations with analysis, insights and strategies to pursue value-driven solutions.
A conversation with François de Brantes

Senior Editor Peter Wehrwein spoke with François de Brantes, M.S., MBA, a member of the Managed Healthcare Executive® editorial advisory board and a senior vice president at Signify Health, recently for our “Meet the Board” podcast. De Brantes has had a long career as an expert on benefit design and cost and quality issues in healthcare delivery. One of the topics they discussed is CMS’ new Direct Contracting Model, which started this month and may have as many as 50 participants, although de Brantes expects that CMS will winnow the group to a smaller number.

Q Is the Direct Contracting Model just another creature in the menagerie of value-based models? Or are we seeing something quite different here?

I think the Health Care Payment & Learning Action Network that was set up as part of the ACA to categorize alternative payment models has done a good job in creating some consistency in how you want to think about alternative payment models. At the far edge of those models are the population-based models. They’re expressed in payment as combinations of different kinds of global payments. The Direct Contracting Model is one of the penultimate expressions of global payment because it truly does involve a per-benefit, per-month payment to a healthcare organization. And that payment should cover the majority — not the totality but close to it — of the care for an individual plan member.

This is actually a relatively big departure from all the other models that the Center for Medicare and Medicaid Innovation — CMMI — has released to date. All the prior models, including the Next Generation ACOs and the Medicare Shared Savings Program ACOs, and even the Medicare bundled payment program — they all still rely on underlying fee-for-service payments.

This is the first time that CMS has said: Look, yes, we’re still going to require provider organization to submit claims, because asking them to stop a known process for a segment of their patients doesn’t make sense. So we’re still going to rely on that stream of data for information purposes but not for payment purposes.

Instead, we are going to give a direct contracting entity a monthly, per-benefit, per-month payment that will cover an estimated portion of the costs for that beneficiary. It is up to that direct contracting entity to contract directly, hence the term, with physicians, typically starting with a primary care group — there’s recognition that at the core, you need primary care — and extending to specialty care groups and others.

Those direct contracts between the DCEs — that’s the acronym for the direct contracting entity — and the providers in that mininetwork can take any shape or form that the two organizations agree to and what the form of payment ought to be. So, for example, you can create a fixed, per-member, per-month fee for the primary care group. You can create fixed-price episode contracts with specialty practices to manage, for example, the cardiac care. So there’s a lot of innovation that you can do within the Direct Contracting Model, much as in Medicare Advantage.

Medicare Advantage plans have the freedom to do lots of payment innovation with the providers in their network. So this is taking Medicare Advantage, for all intents and purposes, into Medicare fee for service and not requiring health plans to be the manager of those funds but allowing provider organizations to take on that responsibility.

However, with that responsibility comes significant risk. And to a certain extent, it is more risk than what happens in the Medicare Shared Savings Program because you are paid upfront a per-benefit, per-month payment. And if during the course of the month, as a DCE, you end up spending a lot more on beneficiaries than what you have been given, you need to float that difference. It’s not as if you’re going to make it up in fee-for-service payments because you’re not going to get any fee for service payments. So it’s a different ballgame.

FRANÇOIS DE BRANTES, M.S., MBA

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The Biden administration put a hold on the new and pending rule changes that the outgoing Trump administration made, so whether the Medicare Coverage of Innovative Technology pathway will ever take effect is uncertain. But many providers and payers — and presumably most device makers — are keeping a close watch on the fate of the pathway. Supporters see it as speeding the adoption of new devices and cutting through a cumbersome CMS coverage process. Detractors, including the authors of an opinion piece published in the New England Journal of Medicine last in March, say the pathway would increase Medicare spending by billions of dollars on devices of uncertain value. The authors of the NEJM piece, which include Joseph S. Ross, M.D., the vice chair of CMS’ Medicare Evidence Development and Advisory Committee, propose instead more FDA and CMS collaboration and a greater emphasis on premarket and postmarketing studies.

CMS covers a device if it deems it “reasonable or necessary” for treating or diagnosing a disease. Some coverage decisions are made at the national level. Others are left to Medicare Administrative Contractors, the private insurers who process claims for CMS. If implemented, the pathway would guarantee up to four years of Medicare coverage of devices approved under the FDA’s Breakthrough Devices Program. Ross and his colleagues leveled some of the same criticisms against the Breakthrough Device Program that critics have of the agency’s breakthrough programs for drugs: the studies are short; the endpoints, surrogates; and the postmarketing studies, not completed for years if at all. More than 400 devices have been awarded breakthrough status because, say the critics, the bar has been set low. Ross and his coauthors say making Medicare coverage automatic for breakthrough devices under this Medicare coverage pathway could “place tremendous financial strain on the Medicare program.” The Biden administration has not signaled how it wants to approach drug and device regulation. Even so, a greenlight for the Medicare Coverage of Innovative Technology pathway seems unlikely. Perhaps the administration will make some of the modifications that Ross and his colleagues suggest.

A couple of years ago, there was a lot of chatter about the Amazonification of healthcare. Well, that hasn’t happened. But the company is breaking into a sector of the economy that accounts for almost 18% of the American gross domestic product. Perhaps healthcare’s journey of Amazonification has started but is going step by step. The latest move was the announcement in March that the company was extending Amazon Care, the online retailer’s telehealth and house call-type service for its employees, to the company’s workforce throughout the country. Previously, Amazon Care was only for the Seattle-based company’s employees in Washington state. Initially, only the telehealth services will be available. The Amazon announcement said the in-person component will get started in the coming months in Baltimore, Washington, D.C., and other cities.

Amazon has more than a million employees throughout the world so healthcare initiatives for its own workers are significant. But this latest announcement also made waves because Amazon said it was opening up Amazon Health to other companies in Washington state (the announcement did not specify on what terms).
Pursuing the holy grail of value-based care? Penn’s LDI says head this way.

Whether the cup of value-based care is half empty or half full may depend on your point of view. But the grail certainly isn’t full. Some of the leading lights at the Leonard Davis Institute (LDI) of Health Economics at the University of Pennsylvania have released recommendations to hasten the volume-to-value healthcare transformation.

Among their more provocative suggestions is increasing the number of valued-based programs that would be involuntary. One of the authors, Hoangmai H. Pham, M.D., M.P.H., said during a webinar in March that there had been an "undue skittishness about deploying mandatory models."

Another author, Ezekiel Emanuel, M.D., Ph.D., discussed the investment of resources and time it takes providers to change to healthcare that rewards quality and lowers costs. “Groups are going to be resistant and reluctant to do that just because of the time — forget the money — just the time and the necessary work that is required,” Emanuel said. “If you have a mandatory model, it takes people over that potential energy barrier.”

Pham and Emanuel were top-ranking health officials in the Obama administration. Rachel M. Werner, M.D., Ph.D., executive director of LDI, and Amol S. Navathe, an assistant professor at Penn’s Perelman School of Medicine and a senior fellow at LDI, are also authors of the 18-page white paper about the future of value-based payment.

Some of their other recommendations for CMS include slowing down the introduction of new programs, designing the models to simplify administration and taking a balanced, "portfolio-based approach," which would mean funding a select number of programs with differing goals. They also say that CMS should favor programs with two-sided risk. "Programs that use two-sided risk (i.e., shared savings and losses) appear to have the greatest impact," according to the white paper.

Healthcare disparities have been on the periphery of ACOs, bundled payments and other programs that CMS (and private payers) have used to advance value-based care. One of the main recommendations from the LDI leaders is to make them central. Some of their specific suggestions include the addition of quality metrics for efforts aimed at addressing healthcare disparities and targeted funding for the care of populations with social risk factors.

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Addressing Disparities

The four historically Black medical schools are part of the answer as U.S. healthcare reckons with racism and inequity.

They are expanding and receiving record levels of donations.

BY LARRY HANOVER
The twin crises of the COVID-19 pandemic and the racial justice outrage sparked by the killings of George Floyd and Breonna Taylor convulsed the country last year. While COVID-19 was killing Black Americans at three times the rate of Whites, African Americans and others protested unjustified killings of Black people by police.

The nation’s four historically Black medical schools have labored throughout their existences to address racial disparities in healthcare and garner respect and recognition. Now, though, the 2020 crises and fresh awareness of how Black Americans historically have been mistreated by the healthcare establishment have resulted in large donations to the medical schools, seeding some hope for breakthroughs in narrowing disparities and training more Black physicians.

The money started to flow in September when former New York City Mayor Michael Bloomberg announced a $100 million gift to be distributed for scholarships for current students at the four historically Black medical schools: Meharry Medical College in Nashville, Tennessee; Howard University College of Medicine in Washington, D.C.; Morehouse School of Medicine in Atlanta and Charles R. Drew University of Medicine and Science (CDU) in Los Angeles.

The gift has created momentum. Morehouse recently announced it is joining up with CommonSpirit Health, one of the country’s largest health systems, in a 10-year, $100 million deal to train more Black doctors. Morehouse plans to establish five new regional medical school campuses as well as graduate medical education programs in at least 10 markets in partnership with CommonSpirit. Meanwhile, Meharry and Morehouse are seeking to double enrollments. All four medical schools report that they are experiencing an upswing in donations.

“I think writ large what’s happening is there’s an epiphany happening among major organizations, corporations and foundations to recognize that the health disparities we’re witnessing — the racial disparities, the bias and all of that — need to be addressed if our whole society is going to advance forward as we’d like it to,” says James E.K. Hildreth, M.D., Ph.D., president and CEO of Meharry.

The leaders of the four medical schools hope the infusion of funds will increase the number of Black doctors. But the goal goes beyond that. By training more Black doctors, they hope to influence the quality of care received by the African American community. Research has shown that Black patients fare better, on average, when treated by a Black doctor than by a White one. Other research has identified race-based misconceptions. For example, a study published in the Proceedings of the National Academy of Sciences of the United States of America in 2016 found that half of White medical students believed that Black patients have higher pain tolerance than White patients.

“Clearly we know that the issues of health disparities are not new,” says Valerie Montgomery Rice, M.D., FACOG, president and dean of Morehouse School of Medicine. “What COVID-19 has done is allowed us to pull back the curtain to see these inequalities and their impact on underserved communities, particularly the Black and brown community. When you add the number of social injustice events that we saw, you had the opportunity for people actually to see it in real time because many of them were on pause from their daily distractions.”

Sources of mistrust

The Bloomberg donation is called the Greenwood Initiative, a reference to the Greenwood community in Tulsa, Oklahoma. In 1921, White residents massacred 300 Black residents of Greenwood, which was nicknamed the Black Wall Street because of the number of Black-owned businesses there.

There is no single source of Black mistrust of White doctors and nurses, although the infamous “Tuskegee Study of Untreated Syphilis in the
Negro Male” looms large. For 40 years, the U.S. Public Health Service conducted a study of 600 Black men, 400 of whom had syphilis that was intentionally not treated. Rebecca Skloot’s book “The Immortal Life of Henrietta Lacks” brought attention to the story of Lacks, an African American woman whose cancerous cells were used without her consent to create the HeLa cell line. Black women were sterilized without their consent during the mid-20th century; the procedures were nicknamed the “Mississippi appendectomy.”

“There’s a legacy, a foundation for distrust,” says David M. Carlisle, M.D., Ph.D., president and CEO of CDU. “When you talk to people about why they have vaccine hesitancy, this is very often cited. They want to make sure that the health system has their best interests at heart, and they’re not sure that’s necessarily the case.”

Low percentages
The legacy of racism is also evident in the racial makeup of the medical community itself. More than 100 years ago, the Carnegie Foundation and the American Medical Association tasked education specialist Abraham Flexner to standardize medical education and anchor it in science. Flexner’s 1910 report resulted in the closing of numerous medical schools, including five of the seven existing Black medical schools. Howard and Meharry were the lone survivors.

Until 2008, only about 2.5% of American doctors were African American; now that proportion is 5%, according to the Association of American Medical Colleges (AAMC). The relative scarcity of Black physicians has persisted in unexpected places, such as Detroit, a city that is now 79% Black. In 2015, a task force found that Wayne State University School of Medicine in Detroit accepted only five African American and two Hispanic students out of a class of 290. It nearly went on accreditation probation for that lack of diversity and other issues but quickly increased those numbers.

“This is not to cast all of them in the same light, but White medical schools have got to do a better job of diversifying their classes,” Hil-dreth says. “Even if Meharry, Morehouse, Drew and Howard all doubled our class size and all of our kids were Black — and they’re not — that still would not move the dial very much. We’ve got to have the other schools doing their part.”

Black men are particularly absent from the physician ranks. White male doctors outnumber Black male doctors 15 to 1. In 2020-2021, only one-third of African American medical school applicants were male, according to the AAMC. School officials hope the new funding coming into their institutions can help them address the issue.

Carlisle called the donations from Bloomberg and others “transformational.” Black students typically have higher debt than Whites because many come from lower-income families. Now every student at the historically Black medical schools not already

![Diagrams showing the racial distribution of physicians and medical school applicants.](image-url)
Historically Black medical schools step forward

The pandemic has galvanized the historically Black medical schools into action. They have played a role in community outreach, advocacy and publicity to spur higher testing and vaccine rates in the Black community. Frederick, Montgomery Rice, Carlisle and Hildreth co-wrote an opinion piece published in the *New York Times* in September that argued for the importance of diversity among the COVID-19 vaccine study volunteers. "As with all drug trials, the impact of medication can differ significantly, depending on the genetic makeup of the population. This is even more so with vaccines that depend on altering the immune system," they wrote.

Carlisle says his school has learned the hard way about the difficulties in getting resources to low-income communities, in which many frontline workers could not social distance and wound up bringing the infection home with them. Last summer, CDU collaborated with county officials and the Los Angeles fire department on setting up and operating drive-through testing sites. But many in the community don’t have cars and some don’t have internet access, meaning they couldn’t schedule appointments. So CDU sent some of its students to neighborhood locations such as malls to try to get individuals tested for COVID-19, Carlisle says. Such outreach helped reduce hesitancy not only among African Americans, but also immigrants who have language barriers and often fear government.

The four historically Black medical schools and other medical organizations have organized several town halls to address the issue of vaccine hesitancy and distrust in the healthcare system, Montgomery Rice says. The events have drawn online crowds ranging from 8,000 to 20,000.

In December 2020, she and CNN’s Sanjay Gupta, M.D., got vaccinated live on the network broadcast. And in January, Morehouse hosted an event where former U.N. Ambassador Andrew Young, former HHS Secretary Louis W. Sullivan and Hall of Fame baseball player Hank Aaron were vaccinated. (Aaron died shortly after from a non-COVID-19-related illness). Throughout the month, the school held “Vaccination Saturdays” for anyone 75 or older. Montgomery Rice says the school had administered 1,800 vaccinations as of late February. It went from having to search for people willing to get vaccinated to a waiting list of 6,000. “We believe we’ve moved the conversation from vaccine hesitancy to vaccine acceptance,” she says.

Hildreth is encouraged by what he sees from the Biden administration, which appointed him to its COVID-19 Health Equity Task Force and made equitable vaccine distribution a focus. “From my perspective, it all comes back to two things: structural racism and implicit bias,” Hildreth says. “We find a way to deal with those things, these problems would take care of themselves.”

Larry Hanover is a freelance writer in southern New Jersey.

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Migraine treatment awash in choices

The triptans, long the workhorses of migraine treatment, have been joined by monoclonal antibodies and small-molecule drugs that block calcitonin gene-related peptide. What’s lacking is a precision approach to treatment based on biomarkers. by JAIME ROSENBERG

The migraine treatment landscape has seen an explosion of new therapies in the recent years and continues to have a robust pipeline, creating a sizable armamentarium of treatment options for the 39 million people in the United States who suffer from the disorder.

Migraine is among the most prevalent illnesses in the world and not only affects quality of life but also productivity, with an estimated 157 million workdays lost each year in the United States. Although there is no cure, there are treatments for both treating migraine at the onset of an attack — known as acute treatment — and for preventing the frequency, severity and length of the headaches. Frequency is one way migraine diagnoses are categorized. Episodic migraines occur 14 or fewer days per month whereas chronic migraines occur more than 15 days per month. The treatments, though, are the same for both. According to Richard B. Lipton, M.D., professor and vice chair of neurology at Albert Einstein College of Medicine and director of Montefiore Headache Center, both in New York City, just one drug is approved for chronic migraine that is not also approved for episodic migraine. So the dividing line in treatment choices relates mainly to whether the medication is being used for acute treatment or for prevention. Acute treatment has traditionally involved analgesics, including the common, over-the-counter all-purpose pain relievers, acetaminophen and ibuprofen. The triptans — Imitrex (sumatriptan), Zomig (zolmitriptan), Axert (almotriptan) and others — are prescribed more specifically for acute treatment of migraine (and occasionally cluster headaches).

The causal pathway of migraines is complex and not completely understood. Even so, it is believed that the widening of blood vessels is associated with the attacks and that the triptans are effective as an acute treatment, at least in part, because they narrow blood vessels.

Preventive treatments have also included beta blockers, which relax blood vessels and prevent their overexpansion; antidepressants; and anticonvulsants.

But despite the many and varied treatments, a large number of people with migraines cannot find one that works well for them.

Blocking CGRP

Migraine treatment entered a new era several years ago. For both acute treatment and prevention, there are now several medications available that block a protein called calcitonin gene-related peptide (CGRP). It is believed that CGRP has a role in migraine because it is involved in the transmission of pain signals and neurogenic inflammation that dilates blood vessels.

The FDA has approved four monoclonal antibodies that block CGRP as preventive agents. Amgen and Novartis’ Aimovig (erenumab-aooe), Eli Lilly’s Emgality (galcanezumab-gnlm), and Teva’s Ajovy (fremanezumab-vfrm) are once-a-month injections that patients self-administer. The fourth, H. Lundbeck A/S’s Vyepti (eptinezumab-jjmr), is administered by a physician every three months.

This new class of treatments represents a major step forward in migraine prevention for several reasons, says Lipton: Their benefits kick in very quickly without a lot of dosing adjustment, they have a favorable side effect profile, and they often work in people who do not respond to traditional preventive treatments. Prior to the approval of the CGRP-targeted
monoclonal antibodies, there was a real unmet need in the prevention space,” says Lipton, explaining that medical claims data have shown that 80% of patients who start on a traditional oral preventive treatment discontinue treatment because it doesn’t work for them, the side effects or both.

In early 2020, Biohaven Pharmaceuticals — a small biopharmaceutical company in New Haven, Connecticut — launched its first-ever product, an oral CGRP-targeted treatment called Nurtec ODT (rimegepant). The approval of Nurtec ODT came a year after the FDA approved another oral CGRP-targeted treatment, Allergan’s Ubrelvy (ubrogepant). (Allergan is now part of pharma giant AbbVie.)

Nurtec ODT and Ubrelvy are small-molecule drugs, not monoclonal antibodies, and they are grouped in the gepants class (pronounced GEE-pants). They have their own list of benefits when compared with traditional treatment. For example, the triptans work by narrowing blood vessels, so they may be contraindicated for patients with heart conditions. These newer treatments do not come with the same cardiovascular concerns. They may also be an option for patients who do not respond to triptans or for whom the side effects are too common or serious.

More CGRP-targeted treatments
Biohaven is also making the case for using Nurtec ODT as migraine prevention. In December, a study published in The Lancet detailed the treatment’s effectiveness as a preventive option when taken every other day. The potential approval of Nurtec ODT for prevention of migraine would create the unusual situation for migraine medicine of the same agent being used for prevention and treatment. Meanwhile, Biohaven has been conducting trials that may get zavegepant, another CGRP-blocking agent, approved as both a pill and as a nasal spray. Biohaven announced the launch of a phase 1 trial of zavegepant last fall and has reported positive results from a phase 2/3 study for the drug as a nasal spray. Delivering a drug intranasally has advantages, explains Lipton. ‘The drug gets into the body faster, so it takes effect sooner. Nausea is a common feature of migraine, so bypassing the digestive system with an intranasal spray might make a drug more effective.

AbbVie’s atogepant may soon be on the market. In July 2020, the company reported positive phase 3 data that showed that it significantly reduced the number of “migraine days” relative to a placebo. An FDA decision was imminent as this issue of Managed Healthcare Executive went to press.

Other targets
The FDA approved Eli Lilly’s Reyvow (lasmiditan) for the treatment of acute migraine in 2019. Reyvow is the first approved ditan (pronounced DIE-tan) a class of drugs that target the 5-HT1F receptor.

Another group of migraine medications in development zeroes in on putitary adenylate cyclase-activating peptide 38 (PACAP-38). Amgen’s AMG-301 was the leading PACAP-38 inhibitor, but results from a phase 2a trial showed that it had no benefit relative to a placebo for migraine prevention. But there are other PACAP-38 inhibitor candidates, including Alder BioPharmaceuticals’ ALD1910. The company has completed enrollment of a phase 1 trial that had 96 volunteers. H. Lundbeck, a Danish company, acquired Alder, which is located in suburban Seattle, in 2019.

Physicians and people with migraine have more treatment options than ever before. This abundance perhaps deflects attention away from a fundamental problem: the absence of an approach to treatment that would be informed, at least in part, by genetics and other individual characteristics.

“The challenge is that migraine is almost certainly more than one disease,” explains Lipton. “We know more than 40 genes that contribute to the risk of migraine and what that may mean is that in different people, migraine has a different mechanism.”

With an absence of established biomarkers, physicians are currently left treating patients on a trial-and-error basis. The problem of lumping migraine patients together affects drug development too. Drugs with a particular mechanism of action may fail if too many patients in the trial have a migraine pathophysiology that is not a good fit with the experimental drug’s mechanism of action. Lipton says researchers are working on identifying subgroups of migraine and treatment responses. Several groups are working on finding genetic and other biomarkers for migraines.

Jaime Rosenberg is a freelance writer based in Jersey City, New Jersey.

“Prior to the approval of the CGRP-targeted monoclonal antibodies, there was a real unmet need in the prevention space.”
— Richard B. Lipton, M.D., Professor and Vice Chair of Neurology at Albert Einstein College of Medicine and Director of Montefiore Headache Center
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Now that the Biden administration is putting a new team in charge of CMS, advocates for accountable care organizations (ACOs) are preparing to push for changes that they say will bolster CMS' ACO programs and make risk sharing more palatable.

The National Association of ACOs (NAACOS) says that ACOs have worked as intended to slow the rate of spending growth for the Medicare program. In January, the group put out a statement saying that the new administration should increase what CMS pays hospitals, health systems and physician groups that participate in the Medicare Shared Savings Program (MSSP) and give them more time to take on downside risk. NAACOS noted that number of ACOs participating in MSSP, the largest CMS ACO program, has dropped from a high of 561 in 2018 to 477 this year.

NAACOS says that MSSP deserves credit for being CMS' largest, most successful value-based program. NAACO President and CEO Clif Gaus, Sc.D., says making the incentives to participate more attractive and the risks more manageable would lead more provider groups to participate. NAACOS has proposed that shared savings be split 50-50 between CMS and the ACOs instead of the current 60-40 ratio. The organization also wants an on-ramp of three years before shared savings starts. "Our healthcare payment and delivery system needs to desperately change, and ACOs offer the leading way to make that happen," Gaus says. "A steady erosion of ACO participation damages our ability to get to where we need to be."

Data that CMS released in September show that the MSSP ACOs had two years of record savings in 2019 and 2018. In 2019, Medicare spent $2.6 billion less than the CMS spending targets for ACOs. The net savings worked out to $1.2 billion after shared-saving payments — money ACOs receive if they spend less than financial benchmarks based on past spending — are factored. In 2018, MSSP ACOs spent $1.7 billion less collectively than CMS' financial benchmarks. The net savings were $740 million after accounting for shared-savings payments and collecting shared-loss payments.

Last June, CMS paused or adjusted many of its value-based programs because of the COVID-19 pandemic and the dramatic decline in the use of healthcare services not related to COVID-19. Among the most significant changes are those that affected Next Generation ACOs. The Next Generation ACO Model, which has 41 participants, gives ACOs a chance to take home higher levels of shared savings, but they are also on the hook for larger shared losses if their spending exceeds their financial benchmarks. ACOs that participate also get waivers from several

Whither the ACO?
The number of participants in the Medicare Shared Savings Program has tapered off, and the Direct Contracting Model may put accountable care organizations at a disadvantage. The National Association of ACOs wants the Biden CMS to make some changes. by JOSEPH BURNS
CMS rules, such as the requirement that admission to a skilled nursing or rehabilitation facility be preceded by a three-day hospital stay. The Next Generation program was supposed to end last year, but the Trump administration CMS, citing the pandemic, granted it a one-year reprieve.

CMS was also gearing up to start the Direct Contracting Model at the beginning of this year but moved out the start to April 1 because of the pandemic. On March 5, the Biden administration said it would stick with that date. As designed during the Trump administration, any provider organization can apply to participate in the program. The model is designed to test two varieties of risk-sharing arrangements. The “professional” track of the program sets shared savings and losses at 50%; the participating provider organization would get half of the difference between a financial benchmark and actual spending if it came in under budget (the shared savings) but also risk paying half of the difference between the benchmark and the actual spend if it went over budget (shared losses). The other “global” track is the full-risk option, meaning providers would get 100% of the savings or pay 100% of the losses.

Have ACOs been aced out?
In a letter to CMS in December, Gauss said that his organization had hoped the direct-contracting initiative would cater to existing ACOs willing to take on more risk. Instead, in Gauss’ view, CMS has provided incentives for health plans to participate in the program and put existing ACOs at a disadvantage.

As designed, the direct-contracting program could cut into the current enrollment in ACOs by allowing new direct-contracting entities to take away members (under Medicare’s patient attribution rules) from ACOs, which, Gauss wrote, have served the Medicare program well for the past decade and have reduced the cost of care.

“These ACOs embraced the transition to value early on and worked with CMS to grow and refine the models so they would be successful long term,” Gauss added. “These providers were on the forefront of the value transition and took great risk to blaze a trail for other providers to follow. Many did so without financial backing and by investing their own resources with uncertainty about a return on their investment. Their commitment to clinical transformation and value-based care has advanced the entire healthcare industry, and they should be rewarded, not penalized, for these efforts.”

America’s Physician Groups (APG) also is aware of these concerns, but APG President and CEO Don Crane, J.D., says his group remains confident about the future for both the Next Generation ACO and direct contracting. His organization, which represents 345 physician groups in 44 states, has long supported CMS’ efforts to promote value-based payment models that use risk sharing, he says.

APG wants CMS to cast a wide net. “We want CMS to move forward with the Direct Contracting Model and with the risk-sharing arrangements in Next Gen ACOs,” he says. “We’re interested in all of the models, frankly. That’s why we say to Medicare, ‘Let’s go forward with these models.’”

Under professional-risk arrangements, a physician assumes the financial risk for the care and services delivered to patients, Crane explains. That’s a lower level of risk than global risk, in which a physician or physician group is responsible for the cost and quality of all the care a patient receives from the health system, whether that care is delivered in a hospital or from a specialist physician.

“What distinguishes APG and its members is that we’re all generally committed to the movement toward value-based care and more specifically to risk-based contracting,” Crane says. “We view capitation as being the ultimate destination for payment. Capitation used to be a dirty word but no longer.”

Joseph Burns is an independent journalist in Brewster, Massachusetts, who covers healthcare.
Dr. Health Plan will see you now

Insurers are taking a hands-on approach to primary care, buying or partnering with practices or setting up their services. by SUSAN LADIKA

The lines have already gotten increasingly blurry between payers and providers as payers have moved to buy or partner with a variety of providers, especially those delivering primary care. And the trend may pick up speed because of the COVID-19 pandemic. Many independent providers have run into cash crunches because of declining patient volumes that may never return to their pre-pandemic levels. Meanwhile, payers are eyeing control of primary care as a way to manage costs and perhaps address healthcare disparities.

“Plans and providers are looking for lower-cost sites of care,” says Kulleni Gebreyes, M.D., a principal with Deloitte Consulting in Charlotte, North Carolina. As a result, “payers are moving from being financiers of care to providers of care.”

“Insurers are going really, really deep into primary care,” says Heidi Leeds, sector leader for health insurance with health insurance consultancy Korn Ferry. “Before they dabbled. Now it’s front and center.” Although some payers “are looking to expand their footprint” by acquiring primary care providers, others are getting involved in the primary care sector through partnerships and joint ventures, Leeds says.

“It’s part of a longer-term strategy,” says Fred Bentley, managing director at Avalere, a healthcare consulting firm in Washington, D.C. Teaming up or acquiring a primary care provider is a means for health insurers to have “even more control and influence over members’ care and engage with them.” The move also is designed to control costs, as “primary care is the gateway to the patient healthcare journey,” Bentley says.

Large insurers are involved

The country’s largest insurers have definitely developed a strong appetite for the insurer-primary care mashups. Humana, for example, announced in March that Conviva Care Centers, one of its wholly owned subsidiaries, was buying a primary care physician network in South Florida that includes 12 health centers and 40 physicians. Earlier in the year, the company announced that another subsidiary, Partners in Primary Care, would add up to 20 new primary care centers in 2021, with locations in the Atlanta and Houston areas, Louisiana and Nevada. Humana said in the press release announcing the Conviva deal that the company now owns 170 “senior focused” primary care centers that are “payer agnostic”—people don’t need to be in Humana Medicare Advantage to be patients at the centers.

CVS Health, which acquired the health insurer Aetna in 2018, has been in the primary and urgent care business for 15 years. The first MinuteClinics in CVS retail outlets opened in the Twin Cities and Baltimore in 2006. Then in 2019, company launched its HealthHUBs, which provide a broader array of services than MinuteClinics and are geared toward chronic disease management. Despite the pandemic, CVS aims to have 1,500 HealthHUBs open by the end of this year.

The company also introduced the Aetna Connected Plan this year in the Kansas City area. Members of the plan don’t get charged at MinuteClinics and HealthHUBs. CVS says the premium is 20% lower than other preferred provider organization products in the market.

UnitedHealth Group CEO David Wichmann said during an earnings call in January that the company’s Optum division started this year with 50,000 physicians and 1,400 clinics and had a goal of adding “at least” 10,000 employed or affiliated...
Zeroing in on seniors

Humana began its push into senior-focused primary care in the Kansas City area, establishing four Partners in Primary Care stand-alone clinics in 2017, and then setting up two clinics at Walgreens drug stores the following year.

The insurer now has four clinics at Walgreens in the Kansas City area and one in South Carolina, says Renee Buckingham, president of Humana’s care delivery organization. After initial concerns over whether consumers would understand that the Walgreens clinics were offering full-service primary care, rather than just urgent care, and whether doctors would be willing to work at a clinic located at a drug store, Humana has been “pretty happy about the retail experience,” says Buckingham. And consumers, particularly those who have mobility or transportation issues are happy to get their healthcare where they can also do some shopping, she says.

Many of Humana’s senior-focused clinics are in Sun Belt locations that have large senior populations. When identifying clinic locations, Humana looks for communities where seniors are underserved by primary care providers, Buckingham says. Care coordination for chronic conditions can suffer where there’s a shortage of providers, she notes, adding that seniors are “one of the most vulnerable populations in the country.”

“The COVID-19 pandemic has made that even more apparent. About 80% of the deaths from the disease have been among those ages 65 and older, according to the CDC.”

Closing healthcare disparities is on many agendas these days. Although insurers have plenty of purely business reasons for moving into primary care — containing costs, capturing a chunk of the premium dollar, forging tighter, multifaceted relationships with members — they also see primary care as a way to address healthcare disparities, says Leeds at Korn Ferry. Through their primary care practices, payers can “serve segments of the population that may otherwise have been left behind,” she says.

Primary care practices with staffs that include behavioral health providers and social workers are in a position to address mental health problems and social determinant of health, says Gebreyes, noting, “They treat the whole person.”

Primary care is also feeling the effects of the shift to some version of capitated, value-based care. Prior to the pandemic, many primary care practices relied on fee-for-service payment. That made sense. “They knew volumes were going to go up,” says Bentley. “That’s not true anymore.”

With a shift to value-based care, “the financing and delivery of care are becoming more interlinked,” notes Gebreyes. It has become something of a truism that physicians who had adapted to value-based care have fared better during the pandemic. Older physicians who have spent their careers in a period when payment was fee for service may be more willing to sell their practices now that value-based payment is taking hold.

For consumers, the shift to value-based care should result in better access to quality care, Gebreyes says, and Leeds says that should benefit insurers: “Every health plan wants to do everything it can to keep the patient out of the emergency room.”

— Renee Buckingham, President of Humana’s Care Delivery Organization.

When identifying clinic locations, Humana looks for communities where seniors are underserved by primary care providers.

— Susan Ladika is an independent journalist in Tampa, Florida, who covers healthcare and business.
If and when someone writes the history of drug pricing in the U.S., the cholesterol-lowering PCSK9 inhibitors are likely to be a paradigmatic chapter. When Repatha (evolocumab) and Praluent (alirocumab) came on the market in 2015, their list prices were more than $14,000 a year. But expectations of wide use and big sales crashed and burned. Payers and, to some extent, physicians bridled at the price of the new drugs, which are administered by self-injection.

The Institute for Clinical and Economic Review (ICER), the cost-effectiveness research organization in Boston, had already made a name for itself in the controversy about the pricing of the hepatitis C antivirals. It weighed in with a cost-effectiveness assessment that said the prices of the PCSK9 inhibitors should be slashed by 60% or more.

“I think it actually just affirmed what many payers and others were feeling, which was that this seemed like an expensive drug for the clinical value that it was going to provide for the average patient,” Steven D. Pearson, M.D., M.Sc., founder and president of ICER, said in a recent Zoom interview with Managed Healthcare Executive.

Starting in 2018, Sanofi and Regeneron, the manufacturers of Praluent and Amgen, which makes Repatha, started to compete on price, and by 2019, the annual price tags of their PCSK9 inhibitors were below $6,000, still more expensive than the price ranges recommended by ICER but less than half of the initial price. In a February earnings report, Amgen stated that sales revenue from Repatha increased by 34% in 2020 compared with 2019, with a 67% increase in volume largely responsible for the uptick. At about the same time, Sanofi reported that sales of Praluent increased by 2.3% in 2020.

So arguably a tick in the win column for tying drug prices to cost-effectiveness — and for ICER — right?

Right price from the start
But last month, when ICER came out with a report on two cholesterol-reducing agents that may compete with the PCSK9 inhibitors, Pearson warned about repeating the mistakes of the past and those early high-priced, low-uptake years of Praluent and Repatha. “We all should just be aware that price and access are joined at the hip,” Pearson told MHE. “It did feel that the first few years after the PCSK9 inhibitors came out, there was an opportunity squandered.”

The two drugs assessed in the ICER report are bempedoic acid and inclisiran. Bempedoic is sold as Nexletol and, in combination with ezetimibe, as Nexlizet. The FDA has held up approval of inclisiran after it found manufacturing problems at a plant in Italy, where the drug is made. ICER says its cost-effectiveness math shows that a fair annual price for the bempedoic acid/ezetimibe combination would be between $1,600 and $2,600, which would be 36% to 60% less than the current wholesale acquisition. ICER’s cost-effectiveness math for inclisiran, which doesn’t have a price yet because it is not the market, put the price tag between $3,600 and $6,000. Pearson said the PCSK9 inhibitors were a hard lesson learned about the dynamics of pricing and wasting the opportunity to bring innovative drugs into clinical use: “If we can get the prices aligned at the front end, that just gets the ball rolling in the right direction.”

Whether inclisiran will be considered to be in the same class as the Praluent and Repatha will be an interesting subplot in the drug’s uptake. It does have a different mechanism of action but works in the same biochemical pathway, noted Pearson. “A clinician would tell you that it serves the same purpose,” he said. One possible advantage of inclisiran is that it needs to be administered only twice a year, albeit by a healthcare professional, in contrast with the once- or twice-monthly self-administered injections of Praluent and Repatha.
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As telehealth has its moment, digital health tools wait for theirs

But many devices don’t communicate with a patient’s electronic health record. by JARED KALTWASSER

For many practices, telehealth used to be something like a treadmill — not the kind at the gym; the kind a person buys based on a late-night infomercial, which then sits in the corner of the basement collecting dust. It’s there. It’s functional. But it rarely gets used.

Though now a common buzzword, the concept of telehealth is decades old. Originally, the term referred to telephone-based check-ins, but over time it evolved to include face-to-face video visits using personal computers and eventually smartphones. As video technology improved, the opportunity for telehealth became too lucrative to dismiss, setting off a cascade of telehealth startups, as well as partnerships with health systems, insurers and tech firms. Even as telehealth became big business, many practices still treated the technology like a novelty. Then along came COVID-19, and telehealth was a novelty no more.

“I do believe telehealth is here to stay,” says Steven Waldren, M.D., M.S., vice president and chief medical informatics officer at the American Academy of Family Physicians (AAFP). He says insurers have indicated an intention not to revert to their pre-pandemic reimbursement levels, and it’s likely that many patients won’t go back to all in-person visits either. The technology is popular with both patients and providers, Waldren says. “There is evidence that patients like virtual visits (because they are) more convenient,” he says.

Last September, AAFP surveyed its members and found that 71% wanted to continue to offer telehealth services even after the pandemic. Victor Camlek, M.L.I.S., principal analyst at Frost & Sullivan, a consultancy, says he also believes telehealth will be a durable part of patient care, although it will take time to see exactly where it slots in. “I think (telehealth) definitely has a good chance to be more visible as we move forward than it was prior to the pandemic,” he says. “But I would like to see more studies that come out and give conclusive evidence that show value and effect.”

So if telehealth is like the treadmill that finally gets used, the question is: Will using it actually lead to something more meaningful than convenience? Will people’s health actually improve?

So smart. But how useful? Camlek’s question is an important one because, unlike a Zoom video call, the call itself is not the goal of a telehealth visit. Rather, the goal is to diagnose and monitor the health of the patient. In a traditional in-person office visit, that would require a battery of tools and devices, from a thermometer to an electrocardiogram. These days, versions of each of those tools can be purchased to use at home, offering physicians a way to extract and act upon data whether meeting in person or electronically. Although the new arsenal of at-home “smart” medical devices is built around communication with a patient’s smartphone, most of these devices don’t yet communicate with a patient’s electronic health record. Nor is it clear that most physicians would utilize the data even if they had direct access to the data.

Just like telehealth before the pandemic, digital health tools are not being widely embraced in medical practices, despite their wide availability. Camlek says a number of barriers are holding back the full integration of digital health tools into routine clinical practice. For
“On the remote monitoring front, we need further standardization of data and their transmission and integration into the (electronic health record).”

— STEVEN WALDREN, M.D., M.S., VICE PRESIDENT AND CHIEF MEDICAL INFORMATICS OFFICER AT THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

As telehealth has its moment, digital health tools wait for theirs

one thing, a line has to be drawn between devices that are for personal use and those that are truly medical. “So there are things underway that will separate telehealth solutions into two categories: those that are endorsed by a body that has stature and the others that are more consumer oriented that you can use but not necessarily rely on for medical-grade precision,” he says.

In the case of the former, regulators, payers and providers will need to decide on clear standards. Ultimately, Camlek predicts providers will want to see evidence “that we were able to achieve similar results to a normal scenario when a patient was treated in person.”

Waldren says that additional data are also needed to know which types of devices are best for each particular practice and, drilling down further, for each particular patient. He says it’s not just data that are needed but also metrics by which to evaluate such data — measurement of measurement. “There is a lack of evidence on how to compare the different offerings in these spaces so that practices can know which are the right solutions for them,” he says, adding that best practices are also needed to standardize effective and efficient operation of such tools.

Setting standards
One of the areas in which digital health integration into patient care has made the biggest strides is in the remote patient monitoring, where digital technology can be used to provide regular, or even constant, monitoring of the status of patients with chronic conditions. Even though the number of remote monitoring devices and services has soared in recent years, Waldren says obstacles remain to integrating such devices fully into regular patient care, telehealth or otherwise. “On the remote monitoring front, we need further standardization of data and their transmission and integration into the (electronic health record),” Waldren observes. “It is still a significant administrative burden to manage multiple devices from multiple companies due to the lack of interoperability and standardization.”

Interoperability has been an important topic in the digital health sector because new federal rules start coming into effect this year. The rules are designed to make it easier for data to travel to and from consumers, their smart devices and providers, but some hospital and payer groups are worried about about privacy and security. They may, however, also be operating out of self-interest; it’s no accident that data tend to get hoarded and siloed.

Privacy concerns
Waldren says the main patient privacy law, the 25-year-old Health Insurance Portability and Accountability Act, is outdated and not in step with the times and people’s attitudes about sharing data. “I think many patients are willing to share their data, not only to help themselves but to advance science and understanding,” he says. “But it needs to be clear what, to whom and for what purposes the data (are) being shared and that rules are in place to ensure that entities follow those rules.”

He points to the eHealth Initiative, a consortium of healthcare companies and associations, including AAFP, as one place in which those conversations are happening. Camlek agrees that privacy concerns and patient concerns about tracking will be an important. “The trade-offs associated with digital health will be crucial conversations, but he says those conversations will differ depending on the health of the patient, the particular condition, and the nature and rigor of the tools in use.

“Things like the number of steps you have taken, it shows you’ve been active, but it’s not a critical decision,” he says. “But if you’re tracking weight remotely and a patient has congestive heart conditions, that could be very important as an indicator that fluid is building up.”

Knowing which tools are available, valid and suitable for a clinical workflow will become critical if telehealth graduates from being an add-on communication tool to being a whole new way of delivering healthcare. Camlek says both patients and clinicians need to be considered: “We need a repertoire of solutions that includes tools that make the patient much more capable of participating in the clinical assessment and the physicians able to interpret data that (they) feel confident in.”

Jared Kaltwasser is a freelancer writer in Iowa.
The U.S. healthcare system spends far more per capita than the healthcare systems of other industrialized nations. Yet the U.S. is notorious for having some of the worst outcomes when measuring health on a population basis. Those outcomes are, in part, a reflection of the country’s failure to address a plethora of unmet social and economic needs — unmet needs that wind up having consequences for people’s health, says Mitchell A. Kaminski, M.D., MBA, director of population health at the Jefferson College of Population Health in Philadelphia.

The out-of-whack ratio between high U.S. healthcare spending and bottom-rung health statistics hasn’t gone unnoticed. All the current attention on addressing the social determinants of health (SDOH) — food pantries, housing programs, transportation vouchers — is a response. Kaminski says the much-talked-about shift from fee-for-service to value-based payment is another adjustment that U.S. healthcare is making. The track record of value-based care is mixed, but Kaminski says the Patient Protection and Affordable Care Act accelerated the shift to it with accountable care organizations and other value-based models.

Partly because of the COVID-19 pandemic, interest in population health has surged. What follows are four trends to keep an eye on.

1. Virtual care: Up, up and not going away
Telehealth, teledicine and remote patient monitoring have transformed access to care and how care is delivered, particularly since the COVID-19 pandemic began, says Allen Miller, M.P.H., principal and CEO of COPE Health Solutions, a healthcare consulting firm in Los Angeles. These trends are here to stay as foundational components of the care model and will continue to disrupt payment models, according to Miller.

Michael Gleeson, chief innovation and strategy officer at Arcadia, a healthcare data and software company in Burlington, Massachusetts, expects telehealth to continue to positively impact healthcare outcomes as it accelerates the shift toward value-based care. This will happen in three stages, he says. First, a combination of technologies and remote monitoring will be used to reduce hospital stays. This will make inpatient hospital stays more effective and improve care coordination between inpatients, outpatients and primary care providers. It will also make patients happier and decrease the cost of care through reduced length of stays, in Gleeson’s view. Second, telehealth visits will catch on, although Gleeson says their popularity will hinge on long-term reimbursement changes, increased levels of patient acceptance and widespread access to technology and internet bandwidth. Gleeson notes that telehealth visits offer a opportunity to engage patients for whom transportation, limited time or mobility may impede access to care. Finally, wearable technology will be used for health monitoring. That will require equipment, but Gleeson says wearables will also require a change in workflows if physicians and other healthcare professionals are to make use of data they produce and for appropriate interventions to be triggered — all while addressing concerns from patients about privacy, surveillance and data use.

As the use of telehealth has grown, so has concern about its overuse. But as larger contracts and

Some of the usual suspects are on the list. And population health itself is trending as a competitive business and an area of study. by KAREN APPOLD

5 population health trends to watch

KAMINSKI

GLEESON

KAREN APPOLD

Population Health

by

KAREN APPOLD
more forces in the healthcare system move to value-based models, concerns about overuse are minimized, says Doron Schneider, M.D., FACP, vice president of population health services at Tandigm Health, a value-based population health company in suburban Philadelphia. Schneider says the incentive structure of value-based care has the effect of curtailing overuse.

2. Spotlight is trained on SDOH

It has become a somewhat tired truism of the COVID-19 pandemic that it has laid bare U.S. healthcare disparities. The pandemic has disproportionately affected Black Americans, and Whites have been disproportionately vaccinated so far. Healthcare providers understand the need to identify social factors that threaten health and wellness and to partner with community agencies to help get patients’ needs met, observes Kaminski.

Lesley Curtis, Ph.D., chair of the Department of Population Health Sciences at Duke University School of Medicine says that helping people emerge from poverty is a current focus of SDOH initiatives. “Poverty inhibits a person’s access to affordable housing, food, employment, education and other social factors that are all inextricably linked to health,” Curtis says. “Poor health contributes to reduced income, perpetuating income-related health disparities. If we focus on addressing poverty through policy and practices that supplement income, (build) educational opportunities, (increase) access to housing and more, there is good evidence that we’ll see big improvements in population health.”

For payers and providers working to create value-based care models and align financial incentives, the highest value is achieved when SDOH data and initiatives are integrated with medical care and premium dollar budgeting, says Miller of COPE Health Solutions.

3. The awakening to racism

The deaths of George Floyd and Breonna Taylor last year led to protests, some rioting and a great deal of discussion about racial disparities and inequities in the U.S. Although racist-driven healthcare disparities have been known in public health and population health for years, Kaminski has recently seen a greater appreciation of how healthcare systems promote inequity through implicit bias and structural racism.

No one is expecting such problems to be remedied overnight, but Kaminski says some changes have occurred. For example, billing codes have been created to capture SDOH issues such as hunger, homelessness and transportation barriers, and in some cases, those SDOH issues are more prevalent among Black and other discriminated groups. Some payers are beginning to provide additional support for those patients. This makes financial sense because by addressing these basic needs, patients can be healthier. In the long run, healthcare costs are reduced when prevention can decrease the amount and severity of chronic diseases in a population, Kaminski says.

Miller believes that one key aspect to closing racial and ethnic disparities and inequities is to ensure that providers for diverse populations reflect the linguistic, cultural and racial profile of the communities they serve. He says this requires education and support to help them achieve professional goals, such as experiential education, mentoring, professional development support and access to entry-level jobs in the

Percent of total population that has received a Covid-19 vaccine by race/ethnicity

White to Asian ratio 1:1
White to Black ratio 2:1
White to Hispanic ratio 2:1

Source: Kaiser Family Foundation. Data are for 39 states as of March 15.
field that provide both financial support and experience to support career aspirations.

4. Messaging is a cage match
The pandemic has also underscored the importance of healthcare and science messages, particularly because whatever messages healthcare officials care to emphasize may be in information combat with conspiracy theories and other misinformation circulating through social media. “During the pandemic, we have seen how misinformation, sometimes promoted for political purposes and capitalizing on public fears, travels at the speed of light and confuses the public,” Kaminski says.

As a result, masks and vaccines have become controversial. Media and social media habits can plant and propagate beliefs that are difficult to disabuse people of. Because of the overwhelming amount of information promoted in media and on social platforms, population health messages need to be conveyed quickly and effectively through the same channels, Kaminski says.

5. Population health itself is having a moment
Knowing where population health trends are headed, most of Miller’s customers are focused on ensuring that they are equipped to manage population health with value-based payment arrangements. This includes potential downside risks and capitation, particularly as CMS’ Direct Contracting Model begins the delayed 2021 performance year. Some industry observers see that program as being a bona fide break from fee-for-service payments.

With value-based payment arrangements becoming more common and the growth in Medicaid managed care and Medicare Advantage, population health has become a business — and a competitive one at that. “Private equity and venture capital money is flowing into the population health space while acquisitions of various key components of population health functionality and networks continue at a rapid pace,” Miller says. Meanwhile, a number of firms called verticals have emerged, focusing narrowly on a particular disease or condition, such as diabetes or high blood pressure, to bring a set of tools to a defined population, Schneider says. Using tools that monitor patients over time, these verticals can help ensure treatment adherence and encourage positive patient progress against a disease.

Academic institutions are also getting on board as awareness in population health grows. “We’re seeing more interest in our masters and Ph.D. programs because students are seeking more rigorous data analytic skills than what a traditional school of public health might offer,” Curtis says. “Employers are looking for students with deep research analytics experience. More students are seeking out academic programs that work directly with health systems like Duke to get real-world experience. I anticipate the COVID-19 pandemic will have lasting effects in so many ways, including a new global focus on population health science.”

Karen Appold is a medical writer in the Lehigh Valley region of Pennsylvania.
When a new medical technology comes along, it ushers in hope that treatment of a disease will improve and that patients will enjoy better health and longer lives. But the march of progress isn’t so sunny and simple these days. New technology also leaves in its wake nettlesome issues such as added cost and whether that cost is worth the benefit, insurance coverage and comparisons with existing technology. Proton beam radiation therapy as a cancer treatment isn’t new at all; the FDA approved it more than 30 years ago. But partly because it involves such a large capital expense, it is still dogged by issues that new technology stirs up. Insurers are being sued for not covering the therapy, and some facilities have struggled financially for lack of patients. A 2018 study of prior authorization for proton beam therapy found that 64% of patients were initially denied coverage and 32% denied after an appeal. Enrollment in clinical trials has often moved at a snail’s pace, partly because many potential participants elect not to participate because the proton beam therapy isn’t covered by their health plan.

Proponents of proton beam radiation therapy can point to some recent developments that put the technology’s situation in a more positive light. Researchers from The University of Texas MD Anderson Cancer Center in Houston reported results last year in the *Journal of Clinical Oncology* that showed the toxicity burden — a weighted sum of the side effects — among 145 patients with esophageal cancer was less for those treated with proton beam therapy than those treated with conventional photon therapy. An accompanying editorial noted that this was the first trial to report a positive primary end point for proton beam radiation in a head-to-head trial with conventional photon radiation. Facilities now are being designed so the investment can be in the tens of millions of dollars rather than more than $100 million. Meanwhile, the Patient-Centered Outcomes Research Institute (PCORI), the nonprofit healthcare research organization funded by fees on insurers, is sponsoring the kind of proton-versus-photon randomized trials that may go a long way toward answering questions about proton beam therapy (although not necessarily in proton beam therapy’s favor).

The COMPPARE study of localized prostate cancer and the RadComp study of breast cancer are recruiting patients. The RadComp trial, which has a target enrollment of 1,278, had enrolled 960 patients as of late March, according to Justin E. Bekelman, M.D., the principal investigator and a professor of radiation oncology at the University of Pennsylvania’s Perelman School of Medicine.

**Photon versus proton**

Radiation therapy damages the DNA of cancer cells so they can’t divide and proliferate. Radiation treatment is effective partly because the DNA of cancer cells is more susceptible to radiation’s effects. And radiation has been part of cancer treatment for more than a century.

Radiation is now increasingly used along with surgery and chemotherapy. A combined approach can increase the chances of preserving the part of the body that has been affected by cancer. For example, lumpectomies to treat breast cancer usually involve radiation treatment after the surgery. Conventional radiation therapy...
uses photons, commonly known as X-rays, to damage the DNA of cancer. Photons penetrate tissue easily and therefore can reach internal organs. Proton beam radiation therapy, as the name suggests, uses protons instead of photons. Protons are the large, positively charged part of an atom’s nucleus.

Radiation therapy that uses photons has become increasingly precise. Intensity-modulated radiation therapy depends on computers to calibrate the radiation so it follows the shape of the tumor and limits the exposure of normal, healthy tissue. Even so, the penetrating power of photons means some of the radiation passes through the tumor. The chief selling point for proton therapy is that it gives off less scatter radiation and that the protons stop at the tumor and don’t exit.

“When we deliver the radiation treatment, we reduce the amount of radiation that goes outside of the target area that you’re treating,” says Curtiland Deville Jr., M.D., medical director of the Johns Hopkins Proton Therapy Center in Washington, D.C. “By doing so, we hopefully reduce the side effects related to the treatment or, alternatively, we can deliver more radiation dose to that target because there’s less dose going into the surrounding tissues.” Deville says proton therapy is an important radiation oncology tool for a comprehensive cancer program, particularly when it comes to pediatric cancer.

Gopal K. Bajaj, M.D., MBA, chair and medical director at Inova Schar Cancer Institute in Northern Virginia, says his health system decided to adopt proton therapy partly because it would help the five-hospital Inova system to compete. “When we were in the process of planning a cancer center of the future, we did a deep dive and evaluated the types of technologies that would be present in a cutting-edge, tertiary care, referral-type cancer center,” he says. “Proton therapy rose to the top as a technology that is truly a market differentiator that patients seek out. It can also serve as a nidus for the growth of other clinical programs.”

Other healthcare systems and hospitals have also heeded the call to build proton beam radiation centers. The National Association for Proton Therapy website lists a total of 38 centers: 34 members, two nonmembers and two members with centers under development — one at the University of Kansas Cancer in Kansas City and the other at the Huntsman Cancer Institute in Salt Lake City.

**Proven but proven better?**
The adoption of expensive medical technology by individual providers to compete for patients is one of the reasons that U.S. healthcare is the world’s most expensive on a per capita basis. Many experts see proton beam as a classic example of an American-style medical arms race. “There’s real harm in spending money on something that’s not better and is more expensive. That harm is a hospital not investing in something else that could improve its community or improve the health of more patients,” Shannon Brownlee, special adviser to the president of the Lown Institute, wrote in a recent blog post about proton beam therapy. The Lown Institute is a think tank in suburban Boston that researches low-value healthcare.

A 2014 assessment of proton beam therapy by the Institute for Clinical and Economic Review (ICER) was not a ringing endorsement. The Boston-based cost-effectiveness group determined that proton beam therapy was superior to surgery for ocular tumors and a safer treatment than photon radiation for pediatric cancers and brain and spinal tumors. But outside of that handful of conditions, the ICER reviewers found insufficient evidence of added benefit for proton beam therapy and also pointed out that it is usually priced two to three times higher than conventional photon therapy. Seven years later, the ICER review is becoming dated. Still, many insurers have continued to deem proton beam radiation for many cancers as experimental and therefore not covered, although those denial of coverage decisions are getting challenged in court. Three cancer survivors have filed a class-action lawsuit in federal district court in Boston against UnitedHealthcare for refusing to cover proton beam radiation therapy. A class-action lawsuit also has been filed against Aetna in Florida.

Penn’s Bekelman says that many payers cover proton beam therapy for childhood cancers, chordomas, brain and spinal cord cancers and selected other indications where there is a consensus that it is medically necessary. But he also referenced the continuing debate about its added benefit for the more prevalent cancers, including breast, prostate, gastrointestinal and lung cancers.

“Proton therapy is a proven treatment for cancer — there’s no doubt about it. Period,” says Bekelman. “However, what remains undefined is whether it is any better than what we currently use, which is photon-based treatment and, most commonly, intensity modulated radiation therapy. That is the debate. It is a proven treatment, but is it proven as better than what we usually do for the prevalent cancers? The answer is not yet.”

Bekelman says the long-lingering questions about proton beam radiation can be traced back, in part, to the FDA having different standards for approving devices than it does for drugs. In contrast to drugs, most devices are approved and come on the market without being evaluated.
Several key studies demonstrated fewer harmful side effects: “In 2020, bigger picture because it produces treatment might produce savings in the showing that proton beam therapy, says recent research is National Association for Proton Maggiore, executive director of the for proton beam therapy. Jennifer But there are other positive findings to help fund research. “[Although] manufacturers do fund radiation-related research, there remains a gap in engagement across manufacturers, providers, insurers and funders on how to pay for proton therapy treatments as part of large definitive randomized trials of this technology,” he wrote in an email.

The results from the MD Anderson study of patients with esophageal cancer stand out because it was a gold-standard study: a prospective, randomized head-to-head trial. But there are other positive findings for proton beam therapy. Jennifer Maggiore, executive director of the National Association for Proton Therapy, says recent research is showing that proton beam radiation might produce savings in the bigger picture because it produces fewer harmful side effects: “In 2020, several key studies demonstrated the promise of proton therapy in making significant and clinically meaningful reductions in acute toxicity in patients.” Bekelman is co-author of a retrospective study of 1,483 patients treated at Penn. The study, which was published in JAMA Oncology in 2019, compared 391 patients who were treated with proton radiation with 1,092 treated with conventional photon radiation. Lead author Brian Baumann, M.D., Bekelman and their co-researchers found that the patients treated with proton radiation were far less likely to have severe adverse events associated with unplanned hospitalizations than patients treated with photon radiation (11.5% versus 27.6%). There was a difference, but less of one, when it came to milder adverse events (74.2% of patients treated with proton beam versus 84.8% of patients treated with photon beam). Results from nonrandomized, retrospective studies such as this come with caution signs against overinterpretation and causal inference. Still, Baumann and his colleagues wrote in the conclusion of the study that the results “at least raise the tantalizing possibility” of cost savings from proton radiation despite the higher upfront price. “Value-based models must acknowledge these benefits and opportunities for long-term savings and promote new and innovative ways to treat cancer,” says Maggiore.

Maggiore acknowledges the expense and time it takes to develop a proton beam facility. Manufacturers have responded by developing single-room systems that are more affordable, she says, and insurers have expanded coverage in the past two years in recognition of the short- and long-term savings. But Bajaj at Inova mentions the difficulties of staffing and keeping costs in line. “Because there are a limited number of proton therapy centers in the country, competition is relatively high for a small and highly trained pool of physicians, physicists, therapists and other clinical staff.”

However, Bajaj says, “if anything, we’ve established through published work over the last decade that there likely is an expanded role of proton therapy in the future of radiation oncology care. I think we’ll continue to see, with clinical evidence development and expansion across disease sites, that increasing numbers of patients will seek it out.”

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Eosinophilic asthma is a type of asthma characterized by an excess of specialized white blood cells called eosinophils in the airways. Classifying asthma is tricky, however, and there is a considerable amount of overlap of the eosinophilic phenotype with type 2 inflammation and atopic inflammation characterized by airway inflammation and mucus production. As a result, some patients with asthma may need multiple treatment modalities.

Waqas Ahmad, M.D., a family physician who runs the medical advisory board of Insurecast, a life and health insurance agency, says patients with eosinophilic asthma suffer from more frequent and more severe asthma attacks. Ahmad notes that eosinophilic asthma is quite rare, accounting for about 5% of all asthma cases and 50% to 60% of severe asthma cases. Acute eosinophilic asthma, which requires systemic corticosteroids or biologics, probably accounts for between 2% and 4% of all asthma cases, according to the American Partnership for Eosinophilic Disorders.

People with eosinophilic asthma tend to have developed asthma at a younger age — often in childhood — than those with other types of asthma, according to Marc C. Gauthier, M.D., assistant professor of medicine in the Division of Pulmonary, Allergy and Critical Care Medicine at the University of Pittsburgh School of Medicine.

Although there are several theories regarding allergen triggers, not all patients with eosinophilic asthma have allergies, and it’s not entirely understood why eosinophilic asthma occurs. Some studies suggest some people are genetically predisposed to developing the condition after being exposed to certain viruses in childhood.

“In general, once established, these patients have persistent inappropriate eosinophil response in the airways,” Gauthier says. “What maintains this inflammation is unclear.”

**Treatment strategies**

Treating patients with eosinophilic asthma revolves around inflammation control and eosinophil inhibition. “This is generally achieved with corticosteroids,” Gauthier says. “For many patients, inhaled steroids, when used consistently, are able to effectively suppress eosinophilic inflammation in the lungs. For patients who require additional treatment, systemic corticosteroids or biologic agents targeted toward eosinophils may be needed.” Bronchodilators such as albuterol are usually not effective as single-agent therapy because they do not address the underlying eosinophilic inflammation.

High-dose, short-acting inhaled corticosteroids may be combined with the inhaled form of long-acting beta-agonists, Ahmad says. When they are not effective, doctors may prescribe systemic corticosteroids, he says. The leukotriene modifiers Accolate (zafirlukast), Singulair (montelukast) and Zyflo (zileuton) also can be helpful, Ahmad says.

For patients with type 2 overlapping inflammation, treatment with Dupixent (dupilumab) is an option. Dupixent is an antibody against the interleukin-4 receptor alpha subunit that blocks both interleukin-4 and interleukin-13 signaling. It quells airway inflammation and reduces the production of mucus.

“For patients with atopy, drugs targeted to mast cells — montelukast against the leukotriene...”
receptor or zileuton against the 5-lipoxygenase enzyme — may be helpful, Gauthier says. "Allergen avoidance may also be of significant benefit, or [introducing] allergen immunotherapy in patients with mild to moderate disease."

Additionally, for patients with severe disease or extrapulmonary manifestations, systemic treatment with corticosteroids or immune suppression may be needed — even with biologic therapy.

"The introduction of biologics in the last five years for eosinophilic asthma has dramatically changed the approach for therapy options," Gauthier says. "Many patients who previously were hospitalized multiple times per year or had frequent emergency department or urgent care visits are now able to stay out of the hospital altogether on therapy. Many have had a significant improvement in their lung function and quality of life. Many patients who had to rely on systemic corticosteroids for years have been able to drastically reduce their dose or wean off steroids completely."

**Three choices**

There are three biologics that directly target eosinophilic asthma via the interleukin-5 (IL-5) pathway. Nucala (mepolizumab) is an anti-IL-5 antibody that directly binds IL-5, thereby preventing it from activating eosinophils. "This is a fixed-dose, once-a-month injection and can be given either in the [physician’s] office or at home," Gauthier says. "The dose was designed to avoid complete elimination of eosinophils, but as a result this can lead to a slight underdose in some patients."

Cinqair (reslizumab) is also an anti-IL-5 antibody that directly binds to IL-5, preventing it from activating eosinophils. It has weight-based dosing, which results in a slightly better efficacy anecdotally in larger patients, according to Gauthier. Some patients say that the effect of the drug, which is administered intravenously, can wear off prior to the next infusion, Gauthier adds.

Fasenra (benralizumab) is an antibody that directly binds to the IL-5 receptor on the surface of eosinophils. It is administered as an injection in the upper arm, thigh or abdomen, and Gauthier says there are formulations that can be delivered with a home injector.

All three of the antibody treatments tend to be more effective in people with higher eosinophil counts, Gauthier says.

Payel Gupta, M.D., FACAAI, an associate clinical professor at SUNY Downstate Medical Center in Brooklyn and Mount Sinai Health System in New York City notes that for people with moderate to severe asthma who have not found relief with other therapies, biologics can help keep them out of the hospital and off oral steroid medications, which pose risks. "The side effects vary, and some people are bothered by injections. On the other hand, the biologics space out treatment, and Fasenra and Nucala can be administered by the patient at home. Of course, insurance coverage is a factor, "Biologics are usually covered by insurance if a patient meets all the necessary criteria for approval, so they should not cost too much out of pocket for the patient," Gupta says. But without coverage, they are not going to be a choice for most patients because of the expense.

Future research into eosinophilic asthma will examine whether other factors play a role in the disease. "Better understanding of the processes behind airway remodeling, exacerbations and overlapping inflammation will help us better understand this phenotype and develop additional therapies for patients who have incomplete responses to the current options," Gauthier says.

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Specialists tend to be valued primarily for their medical expertise, so when a physician takes time to get to know a patient, the doctor is usually praised for having a good bedside manner. But growing evidence shows that knowing about a patient’s life is also crucial to quality of care. For cardiologists, familiarity with those social and educational realities may mean the difference between ineffective care and achieving desired health outcomes.

Sonia Anand, M.D., Ph.D., a professor of medicine and epidemiology at McMaster University in Hamilton, Ontario, Canada, told Managed Healthcare Executive® that social determinants of health (SDOH) should play a critical role when physicians create care plans. “The physician needs to understand their patients’ SDOH situation to choose the medications, follow-up plan and future appointments,” she said. Anand noted, though, that time constraints may make it difficult for physicians to ask questions related to SDOH. Still, there is significant evidence that SDOH are not properly attended to. Results of a study reported in the Journal of Health Care for the Poor and Underserved in 2015 showed that one-third of patients had uncertain access to food, housing or money to pay bills, yet less than half (41.6%) of patients said their physicians were consistently aware of those struggles.

Even when SDOH screenings take place, physicians may have difficulty translating the information into useful decisions. While various indices are available to help physicians account for SDOH, Monika M. Safford, M.D., of Weill Cornell Medicine in New York City, New York, told Managed Healthcare Executive® that regional differences can affect those scores in ways that make it difficult for a physician to interpret on a case-by-case basis.

But it turns out that merely tracking the number of SDOH problems a patient has may yield some insights, even if the physician cannot fully quantify the impact of any single factor. Safford and her colleagues recently published a study in Circulation that involved correlating SDOH data and coronary heart disease (CHD) outcomes in more than 22,000 patients. Adjusted for age, the data showed a clear increase in risk as the number of social determinants increased, regardless of the type; for instance, the incidence of fatal coronary heart disease events per 1,000 person years was 1.30 for people with no SDOH problems and 2.86 for people with three or more. For nonfatal myocardial infarction, the rate per 1,000 person years was 3.91 among people with no SDOH problems, but 5.44 among people with two or more. “(A) simple count of widely available (SDOH) may be a novel approach to identify individuals at high risk of incident CHD events that could be used in the course of clinical care,” Safford and her colleagues wrote.

The results suggest that even a basic SDOH interview could translate into meaningful results. “Education, where they live, whether the area is in a physician shortage area, which state you’re in, how isolated they are socially, their race/ethnicity, their health insurance — all these are recommended parts of the social history,” Safford said. “So, in a nutshell, the information we included in the study should be routinely collected as part of high-quality healthcare, albeit indirectly for annual household income.”

Knowing SDOH is Good Medicine

Paying attention to the social determinants of health may be a powerful way of improving cardiovascular outcomes.

by JARED KALTWASSER
How to fix MS step therapy, prior auth

Senior Editor Peter Wehrwein spoke with Dennis Bourdette, M.D., FANA, FAAN, recently for the MHE Talks Improving Patient Access podcast. Bourdette is a professor and chair emeritus of the department of neurology at Oregon Health & Science University in Portland and founding director of the Multiple Sclerosis Center there. Here are some excerpts from the transcript of that interview.

Early access and approval issues
I would say in general access was not an issue that we worried a whole lot about, aside from occasionally needing to get permission for coverage of an MRI scan.
That changed dramatically in 1993 when the first MS disease-modifying therapy, Betaseron (interferon beta-1b), was approved. People were shocked at the annual price, which was $8,000 a year. Not only were payers shocked, but I think physicians were as well. There was a lot of discussion among neurologists whether this drug was really worth the cost.

Then there were two more drugs approved the next few years, Avonex (interferon beta-1a) and Copaxone (glatiramer acetate injection). So for a number of years, we had three drugs to choose from and their prices were pretty stable, running between $8,000 and $10,000 wholesale a year. The payers required documentation but it wasn’t too onerous.

Drugs prices start to climb
The increases began in 2002 with the release of a third interferon, Rebif (interferon beta-1a), which was brought on the market at a price that was 50% higher than the first three drugs. Tysabri (natalizumab) was re-released in 2006 and there was another upward inflection in prices. Prices increased again in 2010 with the introduction of the first oral drug, Gilenya (fingolimod).

The payers began to require more documentation, and then started coming up with tier systems that complicated our care of our patients and ended up taking more and more of our staff time with the documentation and appeals process.

Preauthorization for tier-one drugs
There are financial reasons for step therapy. There are understandable reasons for cost control and that’s one way to do it. I think some of the frustrations could be dealt with. Requiring us to go through the paperwork and preauthorization for tier-one drugs is a big waste of time because they are going to approve them anyway. And yet, we have to get preauthorization and reauthorization once a year for the tier-one drugs.

Some patients should be put on higher efficacy drugs from the start
There’s a group of MS specialist that thinks everybody needs to go on a higher-efficacy drug because that’s how we’re going to control the disease. We take a more nuanced approach, because there are clearly people who will do well with safer, lower efficacy drugs, long term. So I’m often comfortable putting somebody on a tier-one drug. But there are some patients, based upon the characteristics of their MS, we know that they’re not going to do well unless they get on a high-efficacy drug upfront, and we often have problems getting approval for that.

So it would be good if there was a way to have some flexibility for that subset of patients — it is about 25% of new patients — who meet certain criteria regarding disease activity, so that we don’t have to step through two or three failures before we get access to the higher efficacy drugs, which include the monoclonal antibodies and Mavenclad (cladribine).

Communication between physicians and insurers
One of the ironies is that the drug companies and biotech companies have all these representatives that meet with physicians, although they’re pretty restricted in what they can do at an academic center. They build relationships for reasons that are obvious. The insurance companies don’t do that. Physicians have terrible, terrible relationships with the insurers because of all the administrative hassles I’ve been alluding to.

We should be having a partnership with insurers, because I think most physicians believe in helping control costs. We understand that’s a problem. We just would like to be more engaged by the insurance companies rather than having these decisions made that perhaps aren’t nearly as logical as they (the insurers) think they are.