

September 14, 2020

- 3 MMIT Offers Visibility Into Emerging IDN Market
- 4 Infographic: Current Market Access to Shingrix
- 6 MMIT Payer Portrait: Sentara Health Plans, Inc.

## Uptake of GlaxoSmithKline's Shingrix May Be Slowed by Part D Cost Sharing

Since GlaxoSmithKline plc's Shingrix (zoster vaccine recombinant, adjuvanted) launched in early 2018, a steady number of adults ages 50 and older have been getting the shingles vaccine. But a confusing patchwork of adult vaccine coverage — one that leads to significant out-of-pocket expenses for many in the vaccine's target population — may be leaving some patients behind, analysts say.

Richard Hughes IV, managing director at Avalere Health, tells AIS Health that commercial plan members can receive Shingrix with no cost sharing, but Medicare Part D members generally face cost sharing of around \$50 or more. Some Medicaid plans don't cover the vaccine at all, he adds. The two-shot Shingrix series costs around \$280 without insurance.

These differences in out-of-pocket expenses hold potentially major implications for new potential adult vaccines in the pipeline, including shots to protect against respiratory syncytial virus (RSV) and for clostridium difficile (c-diff), Hughes says.

*continued on p. 3*

## UnitedHealth Drops Descovy as Teva's Generic Truvada Shakes Up PrEP Class

UnitedHealthcare is dropping coverage in its commercial plan formularies for Gilead Sciences, Inc.'s HIV pre-exposure prophylaxis (PrEP) medication Descovy (emtricitabine and tenofovir alafenamide), steering patients instead to Gilead's Truvada (emtricitabine/tenofovir disoproxil fumarate) as a generic version of Truvada is set to launch.

Other plans are likely to follow suit in their PrEP formularies when Teva Pharmaceutical Industries Ltd. releases its generic version of Truvada on Sept. 30, one industry insider says. But formularies could be shaken up again in 2021 as an "A" rating from the U.S. Preventive Services Task Force (USPSTF) for PrEP takes effect, requiring plans to provide health plan members at high risk of HIV with access to PrEP without copayments or deductibles.

In addition, the PrEP pipeline is robust, says Richard Hughes IV, managing director at Avalere Health. "Multiple oral PrEP medications and generics are expected to come to market in the future, and other novel products and formulations are currently in the pipeline," he tells AIS Health.



It's not surprising that UnitedHealthcare would be switching patients from Descovy to Truvada in anticipation of the generic's availability, says Mesfin Tegenu, president of PerformRx.

"Typically, generic products, when clinically equivalent, provide better cost-effectiveness compared to branded products. In this case, if the cost is significantly lower, I would anticipate many other plans would consider preferring the generic product," Tegenu tells AIS Health.

Still, he notes that some states, along with Medicare, have regulations on how HIV treatments should be managed, and "many plans and states have historically opted to keep an open formulary when it comes to HIV treatment."

### **Gilead Increased Market Share in 2020**

Gilead enjoyed a boost from Descovy in the second quarter of 2020, Chief Commercial Officer Johanna Mercier said during the company's July 30 earnings conference call. "For PrEP, we achieved our goal of 40% to 45% Descovy conversion with 43% at the end of June," she said. "We continue to believe that physicians and patients are benefiting from choice and are increasingly seeing Biktarvy [bictegravir, emtricitabine & tenofovir alafenamide] for treatment and Descovy for PrEP as the preferred option for their patients."

Descovy had a 37% market share for PrEP at the end of the first quarter, and closed the second quarter with a 43% market share, Mercier said.

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Teva's generic version of Truvada will have exclusivity for about a year. One component, tenofovir disoproxil fumarate, is now off patent, while the other,

emtricitabine, will lose patent protection in 2021. Several generic versions of Truvada have been approved by the FDA but are not yet on the market.

UnitedHealth has been paring back coverage of Descovy since late 2019, when it implemented step therapy for the drug in some plans, according to plan documents. Members were required to try Truvada before the plan would approve Descovy. United also said at the time that it would approve the drug if the patient has a history of intolerance or contraindication to Truvada.

This summer, UnitedHealth notified providers and members that it would exclude coverage of Descovy from all its commercial plans for PrEP as of Sept. 1 and instead would favor Truvada, plan documents show. Providers still can apply for medical exceptions for members who cannot take Truvada for PrEP, according to the insurer.

### **Drugs Have Different Safety Profiles**

Truvada is approved for all adults and adolescents for PrEP, and Descovy is approved only for use among men and transgender women. Truvada and Descovy also have different safety profiles, according to the white paper.

Chronic use of Truvada is associated with a negative impact on kidney function and bone loss, while Descovy showed statistically significant improvements in renal and bone lab parameters in clinical trials when compared with Truvada, the white paper said. If Descovy receives a recommendation from USPSTF for PrEP, its use should be limited to those with bone disease and/or renal failure, according to WithMe Health.

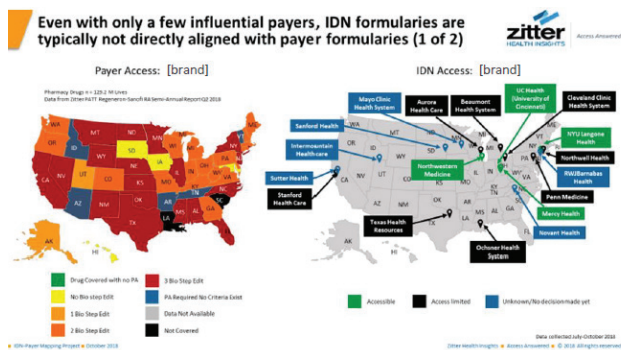
According to AVAC, a global advocacy organization for HIV prevention, products in the PrEP pipeline include oral pills, vaginal rings, vaginal and rectal gels, vaginal films and long-acting injectable antiretrovirals. Several products, including Gilead's long-acting capsid inhibitor, lenacapavir, are in Phase 3 trials. Lenacapavir could allow dosing as infrequently as every six months. ✧

*by Jane Anderson*

## MMIT Offers Visibility Into Emerging IDN Market

As care delivery in the United States continues to shift from fee-for-service to fee-for-value, understanding integrated delivery networks (IDNs), formal systems of providers and sites of care that often offer insurance products, has become crucial to building successful market access strategies. The IDN landscape is relatively new territory for pharma stakeholders, and the market is experiencing constant change as IDNs make acquisitions and consolidate, establish sites of care in new markets and launch more sophisticated value-based care arrangements.

Pharmaceutical management and formulary coverage is particularly difficult to decipher in the IDN market. Data is scarce, as there is no comprehensive reporting system for formulary coverage within hospital systems, and IDN formularies are typically not directly aligned with payer formularies. This can be a challenge for pharma clients looking to analyze medical benefit coverage, gain new contracting arrangements or monitor coverage of competitive brands.



Sample image from IDN Insights

In this climate, scouring hospital formularies and analyzing claims data is simply not enough. To address these challenges, MMIT's IDN Formulary Insights mines survey data from pharmacy directors at more than 125 health systems. Using this data, we create a unique profile for each IDN that describes the formulary decision-making process, creating a map of systemwide formulary stakeholders and their influence on drug coverage. The profiles also contain indication specific information, including formulary preferences, current contracting arrangements, openness to new

contracts and the level of formulary control at individual sites of care within the IDN. Formulary Insights also offers expert consultative support, customizing IDN analysis based on clients' business questions.

Whether clients need to identify which IDNs are managing their products or keep tabs on competitors, MMIT's IDN Formulary Insights provides unparalleled visibility into health system formularies, decision-making and contracting to enable superior market performance with these complex stakeholders.

To learn more about IDN Formulary Insights and other IDN-targeted products, reach out to MMIT's sales team at [sales@mmitnetwork.com](mailto:sales@mmitnetwork.com). ✦

## Part D Issues Slow Shingrix Use

*continued from p. 1*

Future COVID-19 vaccines are set to be covered under Medicare with no cost sharing, he points out. But Shingrix and other adult vaccines in the pipeline are covered under Medicare Part D, which allows co-payments and deductibles to be applied. It would take legislation from Congress to eliminate cost sharing for adult vaccines under Part D.

The differences in coverage result from policymaking decisions made beginning three decades ago or more. Back in the 1980s, Hughes explains, only two primary vaccines for older adults were on the market: the pneumococcal and influenza vaccines.

## Older Vaccines Had the Same Issue

Federal lawmakers decided to require coverage for those two vaccines under Medicare Part B, and "so that means that seniors have access to flu and pneumococcal vaccines with zero cost sharing," Hughes says. When the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 created Medicare Part D, Congress opted to cover future adult vaccines under that program, Hughes says, adding, "then you did start to see innovation — we saw the first acellular pertussis vaccine come out and we saw the first shingles vaccine [Zostavax] come out."

Next came the Affordable Care Act (ACA), approved in 2010, which mandated commercial market cover-

age, without cost sharing, of adult vaccines that are recommended by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices.

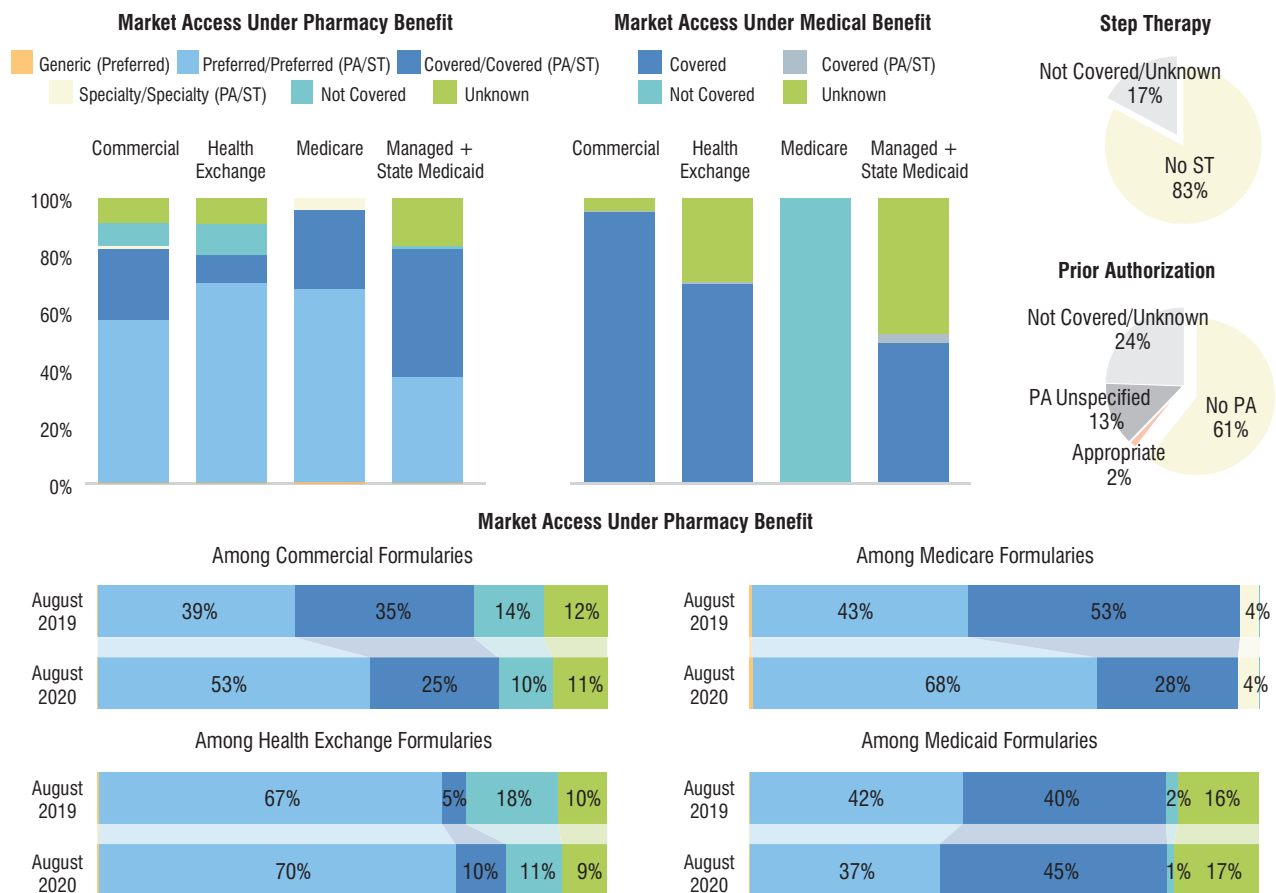
Additionally, the ACA mandated zero cost-sharing coverage of adult vaccines for those covered by the law's Medicaid expansion.

Therefore, adults in commercial and ACA plans can receive recommended adult vaccines with no cost sharing, but Medicare members who have Part D face cost sharing when they receive Shingrix, Hughes says. Some Medicaid populations may not have access to coverage for Shingrix at all, since those decisions are made on a state-by-state basis.

### Current Market Access to Shingrix

by Jinghong Chen

Sales of GlaxoSmithKline plc.'s vaccine Shingrix plummeted in 2020, as few people ventured out for vaccination amid the coronavirus pandemic. For the shingles vaccine, more than 75% of covered lives are under the preferred tier/preferred with prior authorization or step therapy and covered tier/covered with PA/ST under the pharmacy benefit across all formularies. Over the last year, the market saw significant shifts in access to Shingrix, with more people getting coverage under commercial and health exchange formularies. The graphics below show how the vaccine is covered among commercial health plans, health exchange programs and Medicare and Medicaid programs, and their utilization management restrictions.



NOTES: Under the pharmacy benefit, the covered lives under commercial, health exchange, Medicare and Medicaid formularies are 171.2 million, 10.5 million, 46.7 million and 63.9 million, respectively. Under the medical benefit, the covered lives under commercial, health exchange, Medicare and Medicaid formularies are 169.3 million, 10.5 million, 48.5 million and 63.9 million, respectively.  
SOURCE: Managed Markets Insight & Technology, LLC database as of August 2019 and 2020.

Mesfin Tegenu, R.Ph., president of the PBM PerformRx, says Shingrix generally is covered without a requirement for prior authorization, although it's limited to patients who are ages 50 and older, based on the CDC's recommendation.

"Medicare Advantage and Part D plans cover Shingrix, with each plan covering the vaccine differently," Tegenu tells AIS Health. "As a result, the cost for a Medicare beneficiary will vary greatly, depending on what type of drug coverage they have and whether they have met their annual deductible."

A study released in July by the CDC found that shingles vaccination among adults ages 60 and older increased from 6.7% in 2008 to 34.5% in 2018. Vaccination coverage was highest for those who were not experiencing poverty and those who had more than a high school education. Non-Hispanic white adults were approximately twice as likely as non-Hispanic Black and Hispanic adults to have ever received a shingles vaccine.

The percentage of adults ages 60 and older who ever had a shingles vaccination ranged from 26.3% in the East South Central region to 42.8% in the West North Central region of the U.S., the CDC said. GlaxoSmithKline struggled to keep up with the demand for Shingrix when the vaccine first was released in 2018, but now supplies of the shot appear to be ample.

### **Some Members Balk at Cost Sharing**

Avalere has analyzed data for Shingrix and for Zostavax (herpes zoster vaccine), Merck & Co., Inc.'s first-generation shingles vaccine, which no longer is marketed. The consulting firm's analysis found a relationship between the level of out-of-pocket expenditure in the Medicare population and vaccine uptake, Hughes says. "What we have seen is, if a beneficiary encounters any cost sharing, they're less likely to get the vaccine," he says. "It's a correlation, not causation, but we've seen that relationship."

Nearly 60% of non-low-income-subsidy (non-LIS) and non-employer group waiver plan (non-EGWP) Medicare Part D members who received a shingles vaccine in 2018 were able to access the shot as a

preferred brand on their Part D formularies, Avalere's data show. Nearly 40% accessed the vaccine as a non-preferred drug or a non-preferred brand, the data show.

Beneficiaries whose plans covered the shot as a preferred brand paid an average of \$50.24 in out-of-pocket costs, according to Avalere. Those whose plans covered the vaccine as a non-preferred drug paid an average of \$78.13, while those whose plans had the vaccine listed as a non-preferred brand paid \$86.90 on average.

### **Pharmacy Is Most Common Site of Care**

The consulting firm's data show nearly all Medicare beneficiaries receiving their shingles vaccine at the pharmacy, although 64% of those shots administered at the pharmacy were prescribed by physicians. Commercial members and managed Medicaid members received more shingles vaccines at primary care offices, but the site of care for commercially covered shingles vaccine recipients is shifting away from primary care, in part to emergency medicine sites, the data show.

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"Physicians have huge disincentives to buy and bill Part D vaccines," Hughes says. "I've seen data that says the proportion of physicians vaccinating in the commercial segment at age 64 is higher than the proportion of physicians that are willing to vaccinate when you have a Part D vaccine."

Primary care practices may refer patients to the pharmacy to receive Shingrix and other adult vaccines, but "what's the likelihood, percentage-wise, you're going to lose a lot of patients that aren't going to get it?" ✦

*by Jane Anderson*



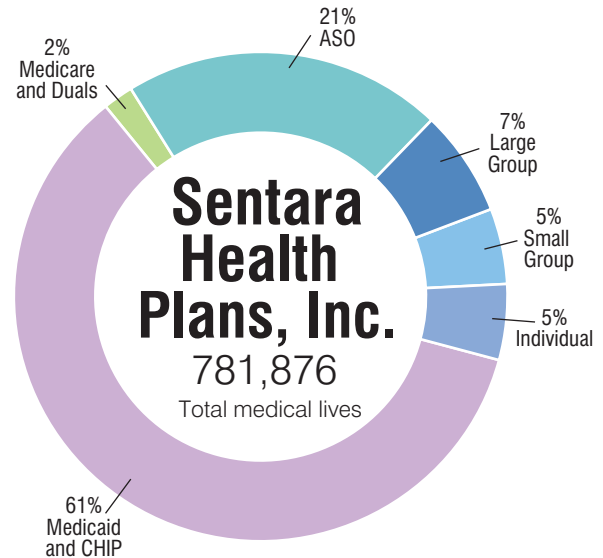
## MMIT Payer Portrait: Sentara Health Plans, Inc.

by Carina Belles

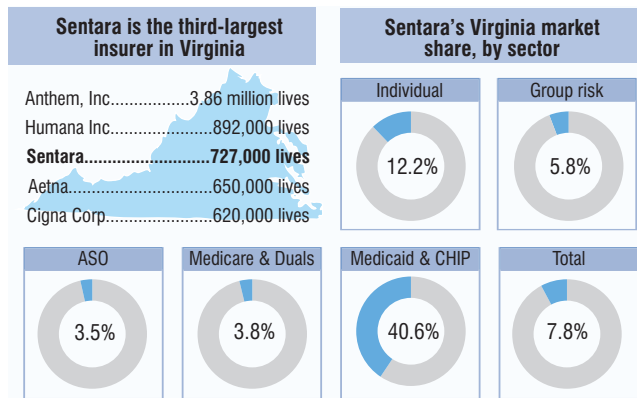
Sentara Health Plans, Inc. is the wholly owned health insurance unit of **Sentara Healthcare**, a Norfolk, Virginia-based nonprofit health system of 12 hospitals and more than 300 other sites of care. The majority of Sentara’s insurance offerings are marketed under its **Optima Health** branding. Sentara’s employer group offerings give it a national presence, but membership is heavily concentrated in Virginia (727,000 members), with smaller markets in Ohio (46,000 members) and North Carolina (6,000 members). **UnitedHealth Group’s OptumRx** and **Optum Specialty Pharmacy** manage Sentara’s pharmacy benefits.

Sentara is a major Medicaid stakeholder in Virginia, with more than 60% of its members enrolled in a managed Medicaid plan. Virginia expanded Medicaid in 2019, creating a more lucrative and competitive Medicaid landscape for payers. Sentara in April 2020 became the majority owner of Virginia Commonwealth University Health System’s **Virginia Premier Health Plan**, the second-largest Medicaid plan in the state, essentially doubling its business.

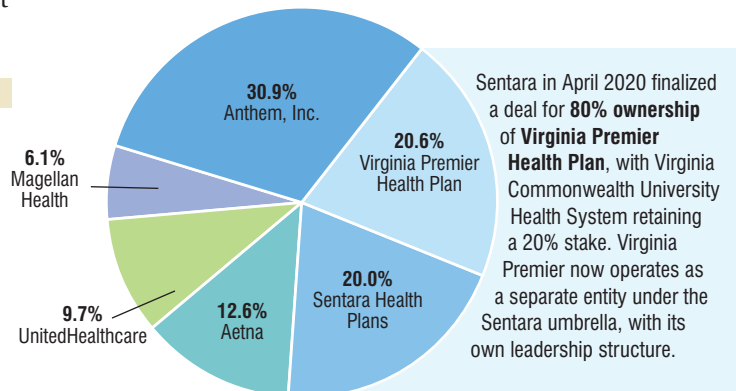
Sentara’s next move is focused on growing its North Carolina business. The company in August unveiled its planned merger with **Cone Health**, a five-hospital system based in Greensboro, N.C. Cone Health also has a small managed care unit, and currently enrolls about **16,000 people** in Medicare Advantage products. Sentara CEO Howard Kern is set to lead the combined organization. In a press release, both orgs pointed out that their current markets “do not overlap,” and claimed a successful merger would lead to more health care options and insurance offerings in both regions. Financial terms of the deal, which is expected to close in the first or second quarter of 2021, were not disclosed. ↩



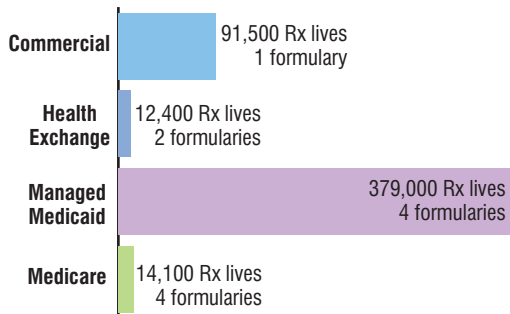
### Snapshot of Sentara’s Virginia Market



### Virginia’s Managed Medicaid Market



### Rx Lives and Formularies by Channel



NOTE: Sentara Health Plans, Inc. and Virginia Premier Health Plan are listed as separate entities in DHP.

SOURCE: AIS’s Directory of Health Plans; MMIT Analytics. Read the press release about Sentara’s merger with Cone Health at <https://bit.ly/3bs9MoP>.

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## About AIS Health

The mission of AIS Health — a publishing and information company that has served the health care industry for more than 30 years — is to provide readers with an actionable understanding of the business of health care and pharmaceuticals. AIS Health's in-depth writing covers the companies, people, catalysts and trends that create the richly textured contours of the health care and drug industry.

AIS Health, which maintains journalistic independence from its parent company, MMIT, is committed to integrity in reporting and bringing transparency to health industry data.

Learn more at <https://AISHealth.com> and <https://AISHealthData.com>.

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## About MMIT

MMIT is a product, solutions and advisory company that brings transparency to pharmacy and medical benefit information. MMIT partners with PBMs, payers and pharmaceutical manufacturers from P&T to point of care. We analyze market access trends and market readiness issues, while providing brand and market access solutions to navigate today's rapidly changing healthcare market.

Our team of experts focuses on pharmaceuticals, business drivers, market intelligence and promotional behavior. Our products and services support brands approaching launch, commercialization efforts, pre-P&T market planning, launch strategy and readiness. We partner with hundreds of payers and manufacturers ensuring that our products continually capture and analyze formulary coverage and restriction criteria for more than 98% of all covered lives.

Learn more at <https://www.mmitnetwork.com>.