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As Multiple Sclerosis Treatment Options Expand, Costs Continue to Balloon

FDA approval of Biogen Inc. and Alkermes' Vumerity (diroximel fumarate) on Oct. 30 made it the third oral disease-modifying therapy (DMT) cleared this year to treat relapsing forms of multiple sclerosis (MS), the most common type. Biogen will sell the follow-on to its MS franchise leader Tecfidera (dimethyl fumarate) at an annual wholesale acquisition cost (WAC) of \$88,000 before rebates — the lowest of any oral DMT in the U.S., the company says. Still, with prices rising yearly at rates 5 to 7 times higher than prescription drug inflation, according to a study published in *Neurology*, DMTs remain one of the highest-spend drug classes for payers.

Express Scripts, a Cigna Corp. subsidiary, said in its 2018 Drug Trend Report that MS ranked as its fourth-highest therapy class in commercial spend last year, eighth in Medicare, 11th in Medicaid and fifth in exchanges. That was despite a decline in per-member per-year spend across the channels, due in part, the PBM said, to members switching from oral Tecfidera to infused Ocrevus (ocrelizumab) after the latter in 2017 became the only drug approved to treat primary progressive MS. Genentech USA, Inc., a Roche Group unit, sells Ocrevus.

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Express Scripts, Prime Therapeutics Team Up to Negotiate Bigger Drug Discounts

Major PBM Express Scripts is teaming up with Prime Therapeutics, a PBM owned by 18 Blue Cross and Blue Shield plans, in a deal that one analyst says should silence concerns that Express Scripts might lose health plan customers after being acquired by Cigna Corp.

Under the three-year agreement, Express Scripts “will provide services to Prime related to retail pharmacy network and pharmaceutical manufacturer contracts,” as the companies put it in a Dec. 19 press release. That means Express Scripts will now negotiate with pharmaceutical manufacturers on behalf of Prime's 28 million members for drugs covered on the pharmacy benefit, in addition to its own 75 million customers.

That arrangement will let Prime “essentially add to and tap into the purchasing power/scale of Express, ultimately allowing for greater rebates from manufacturers, and aid in retail network contracting,” Citi Research analyst



Ralph Giacobbe wrote in a Dec. 20 note to investors. The collaboration, he said, “represents a transparent... pass-through model as rebates are fully passed on to Prime,” while Prime can also tap into Express Scripts’ retail network, contracting with Cigna and collecting a fee for its services.

However, each company will continue to separately manage “certain relationships on the medical benefit” and value-based contracting, the press release said. The firms’ “other relationships with members, caregivers and key stakeholders” will also remain independent.

Ken Paulus, president and CEO of Prime, said the collaboration with Express Scripts “will improve outcomes while still maintaining flexibility and transparency to the clients we proudly serve.”

More Financial Results Coming in 2021

Express Scripts said in the release that it expects its relationship with Prime to have an “immaterial impact” on its earnings in 2020, “with a more positive contribution beginning in 2021.”

“We view this as a significant favorable development for Cigna and most important for sentiment as [Cigna’s] ability to retain health plan clients has certainly come into question following its combination with [Express Scripts], despite strong retention figures,” Giacobbe advised. “The announcement is clearly an indication of a large sophisticated customer acknowledging the value and benefit of partnering with [Cigna/Express Scripts].”

Indeed, Express Scripts President Tim Wentworth said the deal “reinforces our position as a health services partner of choice for health plans, employers, government and other payers seeking the most value for their investments in health care.”

During its third-quarter 2019 earnings call, Cigna gave considerable credit for its strong financial performance to the addition of Express Scripts, which the insurer acquired in 2018. The company said it’s projecting a 97% customer retention rate in 2020 for its health services segment, which houses its PBM division. ✦

by Leslie Small

Express Scripts Names 15 Products for Digital Formulary

Cigna Corp.’s Express Scripts PBM has unveiled the first 15 digital solutions on its stand-alone “digital health formulary,” targeting eight common chronic conditions: anxiety, asthma, depression, diabetes, hypertension, insomnia, prediabetes and pulmonary disease.

These solutions include products from six companies: Livongo Health, Omada Health, Inc., LifeScan, Inc., Learn to Live, SilverCloud Health and Propeller Health, Express Scripts says. They will engage with patients in a variety of ways, such as allowing a pharmacist or nurse to remotely monitor a patient’s use of a drug therapy.

Express Scripts’ new digital formulary, announced in May 2019, may portend new partnerships — and scrutiny — in this space, says Ashraf Shehata, KPMG national sector leader for health care and life sciences. “There have been a lot of digital therapy providers in the marketplace,” Shehata tells AIS Health. “Maybe this is a peek into beginning to see where this is going to go.”

Shehata says he expects to see digital formularies “across the board,” not just at Express Scripts. “These are considered an extension of PBMs’ role. The expectation could be more transparency in this space as we begin to see greater and greater customer adoption.”

New Tools Allow for Greater Oversight

The solutions engage with patients in a variety of different ways, the PBM says. For example, some may allow a pharmacist or nurse to remotely monitor a patient’s use of drug therapy, while others sync to diagnostic devices that provide patients and their caregivers with information on blood glucose or blood pressure, and alert them to potential concerns.

A total of 15 products made the cut for the first digital formulary, Express Scripts said Dec. 12:

- ✦ **Livongo** will have preferred status on the formulary for its diabetes, diabetes prevention and hypertension products. The apps record blood sugar and blood pressure readings, along with

daily step counts; analyze the data for patterns; and provide real-time feedback to patients.

- ◇ **Omada Health** will have preferred status for diabetes, diabetes prevention and hypertension digital care programs. The programs include professional health coaches for one-on-one guidance; cellular-connected devices, such as scales, blood pressure monitors and glucose monitors, that sync to patients' accounts; and weekly online lessons on healthy living and skills for patients to self-manage their conditions.
- ◇ **LifeScan OneTouch Reveal Plus**, powered by Welldoc's BlueStar platform for diabetes, also made Express Scripts' list of preferred products. As part of the program, blood glucose data can be transmitted automatically from the OneTouch Verio Flex glucose monitoring system to the app using Bluetooth. The product also includes individualized real-time coaching.
- ◇ **SilverCloud Health** and **Learn to Live** each will have a digital mental health platform for depression, anxiety and insomnia on the formulary. Both are designed to reduce barriers to accessing mental health services for patients.
- ◇ **Propeller Health** was the only company chosen by Express Scripts to deliver digital health programs for asthma and chronic obstructive pulmonary disease (COPD). The two companies first partnered in November 2017 to provide Propeller's digital solution to Express Scripts members using Bluetooth-enabled inhaler sensors and a mobile app to manage COPD or asthma. Express Scripts members who participated in an early-stage version of this solution saw an 82% reduction in average rescue events per day and a significant improvement in adherence to their asthma controller medication, according to Propeller Health.

Express Scripts says it reviewed more than 70 digital health products for this first round of the formulary, in a four-stage process that tested each product for clinical effectiveness, user experience, security and privacy compliance, and value and affordability. ✧

by Jane Anderson

More MS Options Hit the Market

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"The MS DMT category has continued to grow since its inception in the early 1990s, when the first injectable interferon was FDA-approved," says Gail Bridges, Pharm.D., director, specialty clinical products, for Express Scripts' specialty pharmacy, Accredo. Since 2010, when Novartis' Gilenya (fingolimod) became the first approved oral DMT, oral options have continued to gain share over injectables, she says.

We are now focused on which medications have a better outcome to justify the associated high costs.

According to Mesfin Tegenu, R.Ph., president of PerformRx, "Overall, the cost of the medications within the class remains high." To control spend in the category, he says, "We are now focused on which medications have a better outcome to justify the associated high costs, which has led us to value-based contracts with drug manufacturers."

Express Scripts expects commercial MS per-member per-year spending to rise over the next two years. Among the factors impacting DMT cost trends, Bridges says, are oral therapies continuing to gain share over injectables, and generic availability driving increases in generic fill rate.

Early and ongoing DMT therapy is the standard of care for MS, a chronic immune-mediated inflammatory disease affecting the central nervous system. There is no cure, but DMTs can prevent or delay disease progression and disability.

DMTs Are Crucial for Treatment

Because individual disease course and response to drug therapy varies widely, the American Academy of Neurology recommends that DMTs be made available to all people with relapsing forms of MS. To improve adherence, it also recommends that clinicians and patients share decision-making for DMT choice.

The MS armamentarium now includes six oral DMTs in addition to injectable and infused formula-

tions. All are approved to treat relapsing forms of MS, which affect about 85% of patients. Cost-per-month WAC prices Tegenu provided to AIS Health for the six approved oral DMTs ranged from a high of \$98,525 for Gilenya on an annualized basis to a low of \$86,800 for Vumerity on an annualized basis. Mavenclad has a novel dosing regimen of four courses over 48 months, with a cost per month for a 7-tablet pack of \$7,233.

Tegenu notes that Vumerity has a distinct chemical structure that converts to Tecfidera's active metabolite in the body. "The only marketable difference between Vumerity and Tecfidera is a slight tolerability advantage" for Vumerity, he says. "Clinical effectiveness is the same."

Generics Make Their Way to Market

Generic versions of the three oldest oral DMTs — Gilenya, Aubagio and Tecfidera — haven't yet come to market, but Tegenu believes Tecfidera could be about "12 months-plus from patent expiration." Mylan Inc. currently is challenging a Tecfidera patent that extends the brand's exclusivity to 2028. However, other of its patents are set to expire in 2020. Tecfidera is Biogen's top-selling drug, with sales last year of more than \$4.2 billion.

In a statement, the National Multiple Sclerosis Society expressed disappointment at Vumerity's announced cost. "Vumerity is an efficacious and tolerable treatment option for people with relapsing MS, but being priced only \$500 lower than the least expensive oral disease-modifying treatment, does not show the commitment to affordable access that we had hoped," said Bari Talente, the society's executive vice president, advocacy.

Vumerity's list price puts it in line with competitors. But the average median WAC for DMTs grew from \$60,000 in 2013 to \$80,000 in 2018, according to the society. As acquisition costs have risen, so has cost sharing. A person with MS spends three times as much out-of-pocket than an average person in employer health plans, the society reports.

"We know that high wholesale acquisition cost prices for MS disease-modifying treatments put a heavy burden on people with MS," Talente added. "Too many

are forced to take on high out-of-pocket costs, navigate through complex systems, and face varied and unpredictable decisions by public and private payers and pharmacy benefit managers."

For people with MS, rising out-of-pocket costs can complicate DMT access and can negatively impact adherence. A study looking at cost trends for self-administered MS DMTs in the Medicare Part D program between 2006 and 2016 found that patient out-of-pocket spending per 1,000 beneficiaries increased 7.2-fold, from \$372 to \$2,673. Results were published in JAMA Neurology in August.

Adherence Is Crucial to Savings

Non-adherence to DMT therapy remains a top cost driver, Bridges says. "Despite non-adherence potentially leading to exacerbations and potentially permanent neurologic consequences, more than 25% of MS patients discontinue therapy within the first three months."

Too many are forced to take on high out-of-pocket costs, navigate through complex systems, and face varied and unpredictable decisions by public and private payers and pharmacy benefit managers.

Engagement with patients to proactively identify and resolve barriers to access is essential to achieving optimal therapeutic outcomes, she says.

Tegenu says that as the DMT market evolves over the next two to three years, "We anticipate increased scrutiny on the new products with emphasis on how they compare to existing therapies. With today's rebate-dominated drug formulary development model, although the class may get crowded with 'me too' drugs, we are not encouraged that unit cost as determined by cost per treatment for 30 days will come down."

"However, we expect value-based models to mature to a meaningful level where we demonstrate outcomes and reduced overall health care costs," he adds. ✦

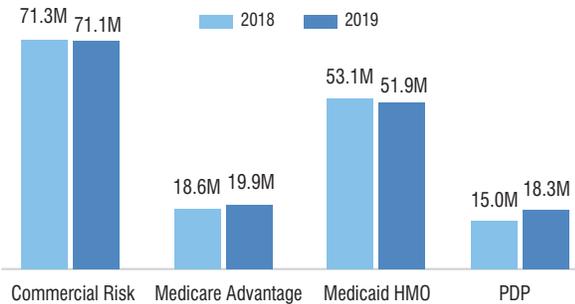
by Sharon Bender

By the Numbers: National Health Insurance Market in 2019

by Jinghong Chen

Over the past year, enrollment in Medicare Advantage (MA) plans and Medicare Prescription Drug Plans (PDPs) saw slight increases, while commercial risk and managed Medicaid membership declined, according to AIS's Directory of Health Plans. UnitedHealthcare holds the largest market share in both MA and PDP markets nationwide, yet its managed Medicaid enrollment dropped by 11.5% over the past year. Following the completion of some major acquisitions, the PDP market experienced significant membership shifts. Graphics below detail the top five insurers in MA, managed Medicaid and PDP markets as of December 2019 and the stock performance of key managed care organizations.

Enrollment by Line of Business



Top 5 Insurers in the Medicare Advantage Market

Insurer	Enrollment in 2019	Market Share	% Change from 2018
UnitedHealthcare	4,973,546	24.9%	5.6%
Humana Inc.	3,767,044	18.9%	14.3%
Aetna, part of CVS Health Corp.	2,262,628	11.3%	32.6%
Kaiser Foundation Health Plan	1,142,783	5.7%	3.9%
Anthem, Inc.	955,497	4.8%	21.7%

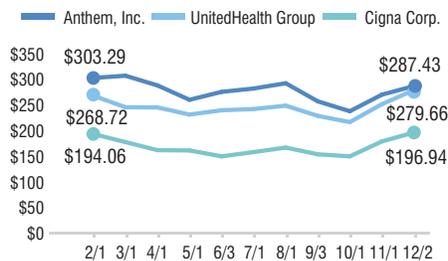
Top 5 Insurers in the Medicaid HMO Market

Insurer	Enrollment in 2019	Market Share	% Change from 2018
Centene Corp.	7,514,579	14.5%	4.3%
Anthem, Inc.	5,416,001	10.4%	1.8%
UnitedHealthcare	4,681,084	9.0%	-11.5%
WellCare Health Plans, Inc.	3,787,529	7.3%	4.2%
Molina Healthcare, Inc.	2,716,699	5.2%	-19.8%

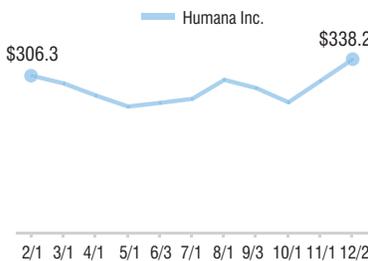
Top 5 Insurers in the Medicare Prescription Drug Plan Market

Insurer	Enrollment in 2019	Market Share	% Change from 2018
UnitedHealthcare	5,015,822	27.5%	11.0%
Humana Inc.	4,217,139	23.1%	-13.2%
Cigna Corp.	3,215,361	17.6%	334.9%
Aetna	2,450,763	13.4%	11.8%
WellCare Health Plans, Inc.	1,685,859	9.2%	64.0%

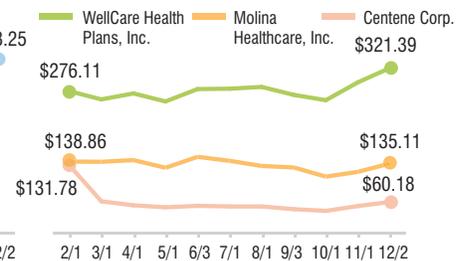
Commercial - Closing Stock Price



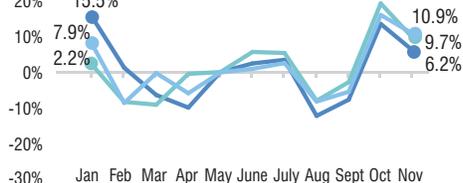
Medicare - Closing Stock Price



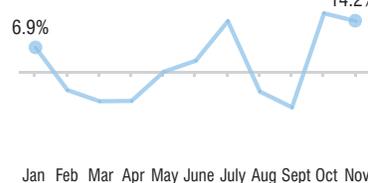
Medicaid - Closing Stock Price



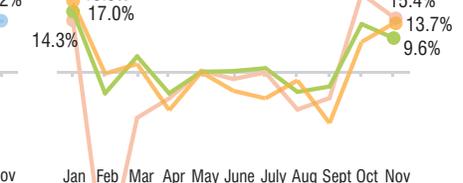
Commercial - Monthly Gain



Medicare - Monthly Gain



Medicaid - Monthly Gain



NOTES: Centene announced a two-for-one split of its shares of common stock in the form of a 100% stock dividend distributed on Feb. 6, 2019. The stock market decline was due to the number of shares issued relative to market capitalization.

SOURCES: AIS's Directory of Health Plans, as of December 2019 and 2018. Bank of America Merrill Lynch.

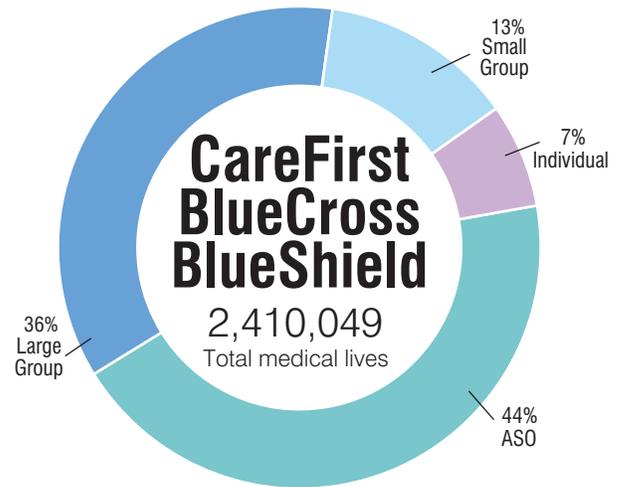
MMIT Payer Portrait: CareFirst BlueCross BlueShield

by Carina Belles

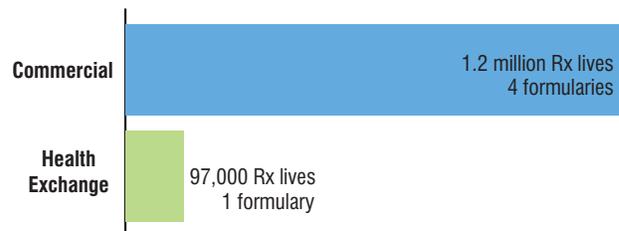
Founded in the 1930s by a Washington, D.C.-based hospital association, CareFirst BlueCross BlueShield is now one of the largest insurers in the Washington metropolitan area, leading the markets in both Maryland and the District itself. It exclusively offers commercial health products, including plans sold on the Affordable Care Act exchanges in D.C., Maryland and Virginia. CareFirst is also the second-largest participant in the Federal Employee Health Benefits Program, behind **Anthem, Inc.**, with about 625,000 members.

CVS/caremark currently serves as CareFirst's pharmacy benefits manager, with **CVS Specialty** handling specialty pharmacy benefits. As of April 2018, CareFirst began managing its behavioral health services in-house, ending its contract with **Magellan Health**.

CareFirst in December 2019 revealed that it will enter the public sector markets for the first time in more than a decade with its planned acquisitions of the Baltimore-based **University of Maryland Health Partners**, and **TRUSTED Health Plan** in Washington, D.C. The two insurers currently enroll **79,819 managed Medicaid members** combined. Following regulatory approval, CareFirst in a press release said its new members will not see any immediate changes to their coverage, and that it plans to integrate both companies into its not-for-profit structure. CareFirst will not acquire the U of M's Medicare Advantage business. Financial terms of the deals were not disclosed. ✦



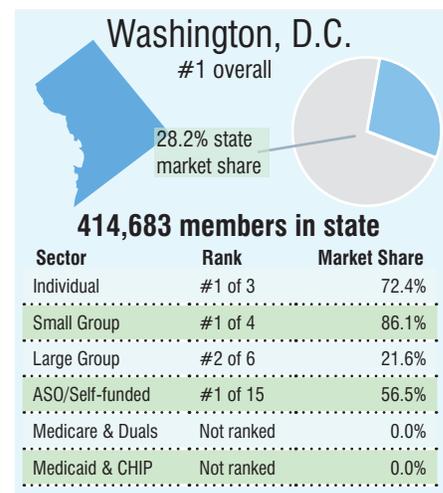
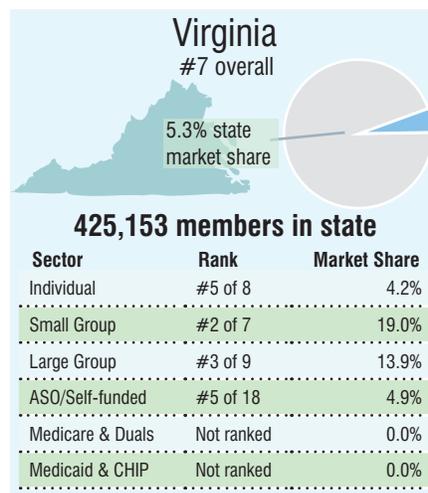
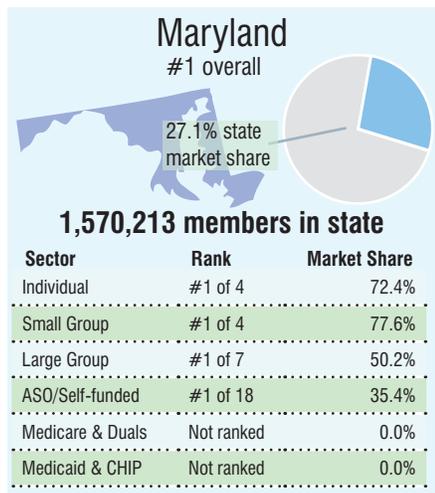
Rx Lives and Formularies by Channel



Another Shot at Medicaid

CareFirst has entered agreements to acquire the **University of Maryland Health Partners** and **TRUSTED Health Plan**, a move that will give the insurer a stake in both the Maryland and Washington, D.C. markets. CareFirst's last foray into Medicaid was its 2009 exit from Maryland's managed care program after several years of financial losses and terminated partnerships with local health systems.

State Market Overview



SOURCE: AIS's Directory of Health Plans; MMIT Analytics

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>.

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>.