MMIT RADAR

Spotlight on MMIT Solutions

Actionable understandings from MMIT's data and applications

February 11, 2019

PBM Inks Deal on Praluent Price, Access

Even as a new study challenges the cost-effectiveness of Regeneron Pharmaceuticals Inc. and Sanofi SA's Praluent (alirocumab), the cholesterol-lowering drug is continuing to win coverage at its reduced price. Still, Praluent faces steep competition from Amgen, Inc.'s Repatha (evolocumab). Given that rivalry, manufacturers' pricing and contracting hold the largest influence over payers' coverage decisions, says one MMIT expert (see box, p. 3).

In May 2018, Express Scripts Holding Co. struck a deal with the manufacturers of Praluent that gave the PBM a lower net price on the drug in exchange for streamlined patient access, a simpler documentation process to secure insurance coverage and an exclusive spot on the Express Scripts national formulary, and an edge on Repatha.

Earlier in 2018, Regeneron and Sanofi said they would lower the net price of Praluent for payers willing to reduce access barriers for appropriate patients. Praluent's manufacturers said they would bring the net cost of the drug down to a range of $4,500 to $8,000 per year, which "represents a very steep discount" off the list price of more than $14,000, said Joshua Golden, area senior vice president at Solid Benefit Guidance, a division of Arthur J. Gallagher & Co.

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In-App Visibility Changes Streamline Access

MMIT's latest Analytics 3 enhancements make coverage source details and month-to-month coverage changes easier to access and identify. A new icon has been enabled to Analytics 3, an optional "S" icon that will take customers directly to a formulary searchable website if the source of formulary coverage is reflected on a payer searchable.

MMIT considers a payer's or PBM's publicly available formulary coverage to be the primary source of all coverage information, and has historically provided downloadable PDFs of these documents whenever possible. However, payers tend to update their websites before posting new PDF documents, which can cause confusion for Analytics 3 users when the coverage specified doesn't match the PDF available. With the icon, users will now be linked directly to the searchable source of coverage information in real time. This feature is optional and will be turned off as a default, so users should contact their client success lead or support@mmitnetwork.com to have it enabled.

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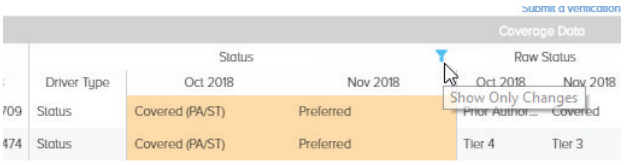
Additionally, we have enhanced our Compare With Another Month view so that changes in lives, coverage status, and prior authorization/step therapy will now be highlighted in yellow. Users can also use a new filter to show only those items that have changed during the selected time period, making analyses easier than ever. The change filter can be viewed both inside the app and in exports. ✧

Formulary	Documents	Lives	Status
Aetna Medicare Formulary A1B	S	1,175,582	Not Covered
Aetna Medicare B2 Formulary	S	514,092	Not Covered
First Health Part D Value Plus	DL	441,861	Not Covered
Aetna Medicare A3 Formulary	DL	279,331	Not Covered
Coventry Health Care B2 Formulary	S	266,717	Not Covered
First Health Part D A3B Formulary	S	119,061	Not Covered
HealthAmerica and HealthAmerica...	S	72,628	Not Covered
HealthAmerica and HealthAmerica...	DL	50,103	Not Covered

Formulary Navigator's new "S" icon



New search filter in Analytics 3

Express Scripts Makes PCSK9 Pact

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However, a Jan. 1, 2019, study published in the *Annals of Internal Medicine*, found that even that reduced price was still too high. The ODYSSEY Outcomes trial evaluated patients with recent acute coronary syndrome, comparing ones receiving only statins against those receiving a statin plus alirocumab or a statin plus ezetimibe. Although those receiving alirocumab had lower rates of heart attack, stroke and death, the researchers concluded that "the price of alirocumab would have to decrease from its original cost of $14,560 to $1,974 annually to be cost-effective relative to ezetimibe."

Golden also warned that payers' costs could rise as a result of the formulary strategy. "Personally, I'm concerned that any financial gains on pricing may be eroded by increased utilization. We're encouraging our plan sponsor clients to pay close attention to PA [i.e., prior authorization] approval and denial rates over the coming year for this class of drugs," he said when the Express Scripts deal was unveiled.

Express Scripts spokesperson Jennifer Luddy said that prior to the announcement, both PCSK9 inhibitors were included on Express Scripts' National Preferred Formulary, which covers about 25 million of the PBM's 83 million lives.

To have a PCSK9 covered, patients had to have familial hypercholesterolemia and "have not achieved optimal outcomes using the highest doses of statin therapy," she said, adding that Express Scripts also collaborated with the FH Foundation on PA criteria "to ensure those patients had easy access. In the CCV program in 2017, 14% more patients achieved optimal adherence to PCSK9 therapies when receiving specialized care from Accredo versus a retail pharmacy setting."

The Express Scripts deal calls for Praluent to hold preferred status with loosened documentation requirements needed for approval. Physicians now must submit a simplified attestation form confirming that Praluent is appropriate for the patient based on the FDA-approved indication and patient history, vs. the extensive utilization management process required by other PBMs, which involves multiple steps and lengthy documentation of lab results and patient history.

Competition Could Lower Prices

Ashraf Shehata, a principal in KPMG LLP's health care life sciences advisory practice in Cincinnati, said he is optimistic that competition between Praluent and Repatha could lower net prices for both drugs. He compared the situation with PCSK9 inhibitors to that of hepatitis C drugs, where high-priced but very effective products dramatically shook up a drug treatment class, and said both drugmakers and PBMs learned from hepatitis C.

The price for hepatitis C drugs dropped by about half once there was competition in the market, he says. "The good news is, we have learned the way the economics of this cycle work," Shehata told AIS Health. "If you keep trying to block availability of the drug, the market tends to respond with an improper price." ✧

by Jane Anderson

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Anthem Hits the Gas on Launch of In-House PBM IngenioRx

Anthem, Inc. caused its stock to surge and Wall Street analysts to raise their 2019 and 2020 earnings estimates by revealing during its quarterly earnings call on Jan. 30 that it's planning to launch its in-house PBM three quarters earlier than it originally projected.

In its earnings release for the fourth quarter of 2018, the insurer said it will terminate its contract with Express Scripts Holding Co. on March 1, 2019, rather than the original expiration date of Dec. 31, 2019, because of Cigna Corp.'s acquisition of the PBM. Anthem now expects to begin transitioning members to the new PBM platform, IngenioRx, in March.

On a call with investors and analysts, CEO Gail Boudreaux said Anthem continues to expect IngenioRx to save it at least $4 billion on prescription drugs once it fully transitions to the new PBM in 2020, with at least 20% of that accruing to shareholders. She also said Anthem is confident in its readiness to launch because the results of its operational testing "have been very positive."

Industry analysts reacted favorably to the news of IngenioRx's accelerated launch. "We are raising our both 2019 and 2020 EPS [earnings per share] estimates by $1.50 to $19 and $21.50, respectively," Credit Suisse's A.J. Rice advised investors in a Jan. 31 research note.

Added Leerink's Ana Gupte: "The solid quarter, strong guidance and most importantly the earlier than planned launch of IngenioRx PBM in 2Q19 with completion by 1/1/2020 show the power of the platform being unleashed under the leadership of CEO Gail Boudreaux." ✧

by Leslie Small

MMIT's Take: PCSK9s

"The proprotein convertase subtilisin/kexin type 9, or PCSK9 inhibitor market, is small in number of manufacturers, but a highly competitive market, between Repatha (Amgen) and Praluent (Sanofi and Regeneron)," says Andrew Sgarlato, a client success lead at MMIT. Sgarlato says that while there is a "perceived lack of marketplace opportunity in this indication," new developments, such as The Medicines Company's partnership with Alnylam to develop a new PCKS9 inhibitor sometime this year, make this space an interesting market to watch. The perceived lack of opportunities in the indication "partially resulted in Pfizer ending their development of a PCSK9 inhibitor in 2016," he adds. "Heavy restriction by payers and lack of perceived market and patent lawsuits tend to minimize the possibility of new entrants within this space."

"While coverage exists primarily in the pharmacy benefit, both the medical and pharmacy benefits face heavy restriction and a complex pathway to receive access to these products," Sgarlato says, pointing to step therapy as a common restriction. "We've also seen payers require criteria such as Low Density Lipoprotien (LDL) levels, lifestyle modifications, and supporting documentation requirements to initiate therapy. This class is also heavily restricted for reauthorization, and requires goals in terms of LDL reduction for patients to continue on therapy."

Sgarlato says given the steep competition between the two manufacturers, pricing and contracting hold the largest influence over payers' coverage decisions, and points to Sanofi/Regeneron's April 2018 agreement with Express Scripts to lower Praulent's price to boost sales and place it on the PBM's National Preferred formulary as a trend-setting deal. "Amgen followed suit in October of 2018 with a price cut for Repatha, primarily hoping to gain access to the product for Medicare patients," he adds. "The difference between the two products strategies was Sanofi/Regeneron issuing their cut in the form of a rebate, whereas Repatha changed the price of the product by offering a separate NDC at that price. Some have dubbed it 'Lopatha' due to the cost difference."

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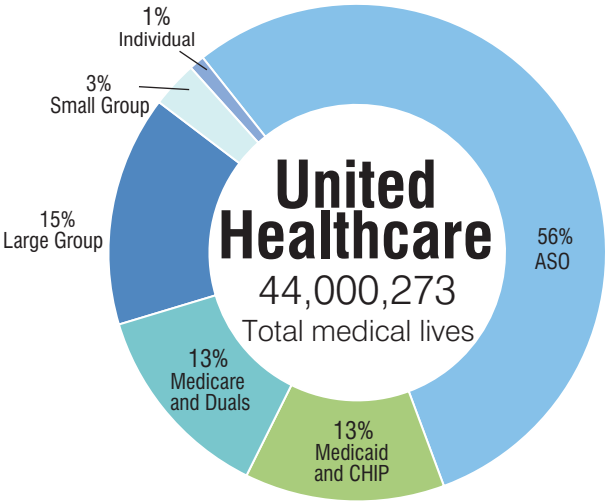
MMIT Payer Portrait: UnitedHealthcare

by Carina Belles

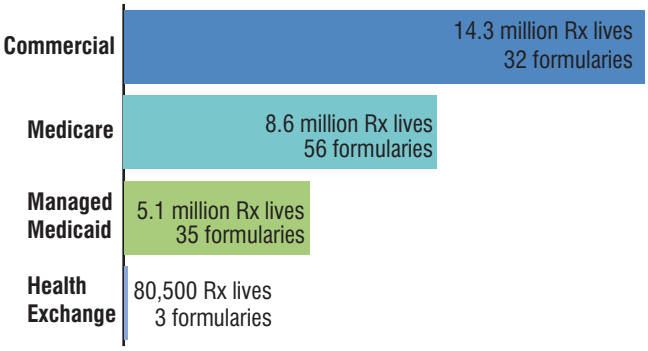
UnitedHealthcare (UHC) is a unit of publicly traded UnitedHealth Group, Inc. offering health insurance products nationwide across every sector. United is the largest health insurer in the U.S., and the market leader in several key sectors, with more than 44 million current members.

UHC has operated its own in-house pharmacy benefits manager, OptumRx, since the 1990s. In addition to United members, OptumRx also serves other health insurers, including **Health Choice Management Company** and **Blue Cross Blue Shield of Arizona**. Across its Optum brands, which include behavioral health management, hospital administration and billing services and other care management entities, United has been a trendsetter in a market ruled by M&A and close integration of health services.

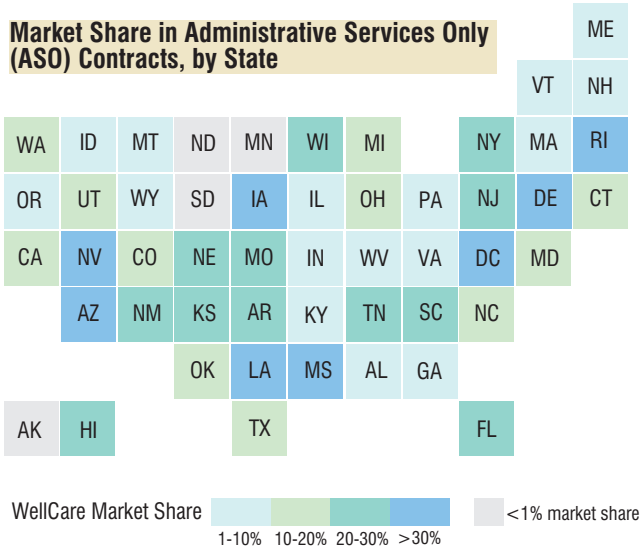
United made key acquisitions in 2018 to boost Optum's footprint, purchasing **Genoa Healthcare**, then the fifth largest pharmacy chain in the country, in October 2018, and **Avella Specialty Pharmacy** in November. As OptumRx has grown, it has become a leading influencer in payer-PBM integration. Recent consolidation activity shows other insurers are gearing up to compete, following CVS Health's acquisition of **Aetna Inc.**, **Cigna Corp.**'s acquisition of Express Scripts, and **Anthem, Inc.**'s imminent launch of IngenioRx, its new in-house PBM. ✧



Rx Lives and Formularies by Channel



Market Share in Administrative Services Only (ASO) Contracts, by State



United Is the Top Insurer in Five Key Market Sectors

Sector	Current Enrollment	Change from 4Q17	Market Leader
Individual	495,000	+5.7%	Centene Corp.
Small Group	1,299,835	+0.3%	UnitedHealthcare
Large Group	6,655,165	+0.2%	UnitedHealthcare
Administrative Services Only (ASO)	24,435,000	+13.9%	UnitedHealthcare
Medicare Advantage	4,708,225	+2.7%	UnitedHealthcare
Dual Eligibles	818,171	+19.6%	UnitedHealthcare
Medicaid and CHIP	5,588,847	-5.9%	Centene Corp.

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

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Spotlight on Payer Membership

by Carina Belles

National Medicaid enrollment has grown **6.59%**, to more than **75 million people**, since 2014, the year many states began expanding Medicaid eligibility under the tenets of the Affordable Care Act, according to the latest update to AIS's Directory of Health Plans. Much of this growth has been concentrated in Medicaid managed care organizations, where enrollment has surged from **50.97 million** in 2014 to **55.63 million** today. Significant growth is expected again this year, when North Carolina begins its new managed Medicaid program in November. Fee-for-service Medicaid, where state agencies reimburse providers for health services rendered based on a fee schedule, has grown only **0.05%**, to **19.82 million lives**, in the same time period.

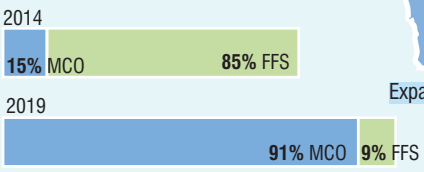
Many states are actively moving away from the fee-for-service system. The cost burdens in traditional Medicaid have become more unpredictable than ever, with large influxes of new members in states that have expanded Medicaid, and drug prices on the rise, particularly for costly new therapies for illnesses that are more likely to affect the Medicaid population, such as Hepatitis C. Rather than push already tight budgets to the limit, states are increasingly entering risk-based arrangements with managed care plans, which can more effectively manage and predict costs.

The shift to managed care has created growth opportunities for insurers, who see managed Medicaid contracts as a stable source of revenue. The bidding process for new managed care contracts is highly competitive, with North Carolina's Medicaid revamp being the latest battleground. Once North Carolina begins its new program, just 10 states will remain entirely fee-for-service.

See a selection of states that have made significant investments in managed care since 2014 and how their Medicaid populations have changed below. ✧

Iowa, 678,000 Medicaid lives
+23.1% since 2014

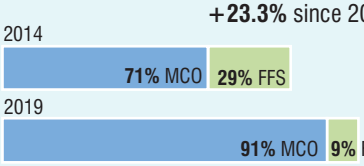
Expanded Medicaid in 2015



Contracted Payers	Current Enrollment	Change from 2014
UnitedHealthcare	419,581	Contract began in 2016
Anthem, Inc.	193,396	Contract began in 2016
Meridian Health Plan	Contract ended in 2015	-100%

Louisiana, 1.63 million Medicaid lives
+23.3% since 2014

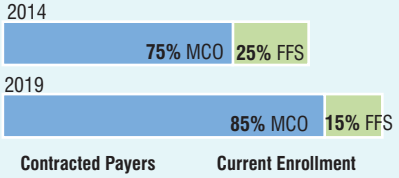
Expanded Medicaid in 2016



Contracted Payers	Current Enrollment	Change from 2014
Centene Corp.	466,243	+31.4%
UnitedHealthcare	438,128	+55.2%
Anthem, Inc.	263,342	+83.7
AmeriHealth Caritas	206,464	+37.0%
Aetna	116,118	+725.9%

Ohio, 2.68 million Medicaid lives
+18.3% since 2014

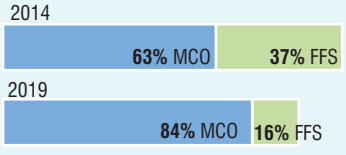
Expanded Medicaid in 2014



Contracted Payers	Current Enrollment	Change from 2014
CareSource	1,194,787	+31.4%
Centene Corp.	291,942	+62.1%
UnitedHealthcare	278,761	+59.3%
Molina Healthcare	274,436	+16.8%
Paramount Ins. Co.	233,461	+48.5%

Utah, 289,000 Medicaid lives
-16.8% since 2014

Voters passed an initiative in favor of expansion in Nov. 2018



Contracted Payers	Current Enrollment	Change from 2014
SelectHealth	104,283	+14.4%
Molina Healthcare	72,167	-3.3%
University of Utah	48,633	+11.7%
Health Choice Mgmt Co.	18,398	+182.5%

AIS's Directory of Health Plans, a unit of MMIT, maintains payer data and tracks enrollment of health insurers each quarter, as well as their PBM and specialty pharmacy contracts. To log into your account, go to https://aishealthdata.com/dashboard/dhp or contact sales@AISHealth.com to have this access added to your account.

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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.

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.

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