MMIT’s Second-Quarter Lives Update Captures Initial Scope of Pandemic’s Impact

In a short period, the COVID-19 pandemic has upended economies, disrupted travel and trade, closed businesses and forced many Americans to remain at home. Despite the massive upheaval, the impact on market access is still unfolding, but MMIT’s second-quarter lives update has captured a piece of the puzzle.

Under normal circumstances, MMIT’s second-quarter lives update captures changes in Medicare, Medicaid and exchange lives allocations, including adjustments in Medicare low-income subsidy beneficiaries, using inputs from CMS publications, market research and client verifications. Our May 11 lives update incorporates those changes, as well as our estimate of the current impact of COVID-related job losses, with an effective date of May 1, 2020 (see table, p. 4).

In the first two months since the nation shut down to reduce COVID spread, more than 20 million lost their jobs. But MMIT estimates that 43%, or 9.5 million, did not have insurance to begin with. Another 28%, or 6.1 million, already were Medicaid recipients. That leaves just 29% — 6.4 million people — who were commercially insured when they were laid off.

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Spotlight on MMIT Team: Stu Allen

Stu Allen is a vice president of product and pharma services at MMIT. He currently works in the business performance group and has been with MMIT since 2013. Day to day, Allen focuses on driving efficiencies throughout the organization related to key corporate initiatives and enhancing MMIT’s solutions to meet the needs of an evolving healthcare industry.

Q: Tell us more about what you do.

A: While I’ve had many roles at MMIT, I am currently part of the business performance group. The goal of this team is to acutely focus on specific challenges or top initiatives for the company and drive change throughout the organization. As an individual, I am tasked with leading two of these initiatives and taking them from where they are today to a state of completeness, as defined by our leadership team and, more importantly, our clients. My main objective is to make the business more efficient wherever the help is needed.
**Q: What’s your day-to-day like?**

**A:** [It’s] a delicate balance between intensive focus on the “needle-moving” initiatives with the “whirlwind” of day-to-day items that come up, which can often be distracting. With my role in the business performance group, I work with multiple departments to facilitate solutions to core business challenges and deliver on those top priorities as soon as possible. This sounds simple, but many of these initiatives involve constant improvement and require sophisticated processes to be put in place so that we can hit key milestones in each area. For some of these efforts, the objective might be to stabilize the process so that ultimately I can transition responsibility to another individual or team and move on to the next thing. Of course, to do this well, I need to ensure that the successor is set up for success. In terms of the whirlwind aspect of my role, you’ll also see me helping to troubleshoot specific client issues.

**Q: What are some of the larger projects you’re working on?**

**A:** I’m specifically working on our client configured fields (CFF) deliverables and overhauling the process and end-state for our clients. This involves streamlining what would otherwise be an extremely complicated process, given the nature of how patient access is evolving. The second initiative involves similar objectives in terms of the simplification and sustainability of our promotional offerings. For this, my personal objective is to ensure that our promotional offerings are stable and that the processes and tools we use to configure those platforms are bulletproof.

**Q: What are some of the common challenges of your role?**

**A:** Any time you have a company that is growing at the rate we are growing, knowledge transfer is really the biggest challenge. There are a lot of things that have been a challenge to get out of my head and into a scalable process or engine that percolates these learnings across the business. There’s a certain level of institutional knowledge, meaning that someone has probably solved a similar challenge in the past. The tough part is identifying similarities in these issues and being able to apply them effectively in a constantly changing world, where they may not look identical.

**Q: What’s been your biggest victory with a client, or with the company so far?**

**A:** This may date me a bit, but my biggest victory tracks back to 2015, when I was tasked with converting our entire pharmaceutical manufacturer client base from our legacy platforms to new applications and data deliverables. This was no simple task, and 2015 marked a major milestone for the multi-year initiative. For those familiar with Analytics and FormTrak, this was before these brands even existed. With the help of our team, I supported the conversion of 100% of our clients. I was able to talk to each and every one of our client stakeholders and familiarize myself with their nuanced business needs. These relationships amplified my ability to enhance upstream processes and technology to meet the needs of these clients. By the end of this two-year effort, we implemented a more user-friendly support interface and built client relationships that would feed MMIT with the insights needed to reinforce the product strategies we still use today.

**Q: What does MMIT do, in your own words?**

**A:** I believe that our vision statement says it all: MMIT smooths access to therapies. When I first heard this from our executive team during our company gathering, it deeply resonated with me and I thought it was a great way to articulate the broader objective of our business. I have evolved significantly at MMIT, and so has the company. I can set my anchor on this vision for the company and say that I work for a company that...
uses data, technology and insights to streamline access to drugs for the patients who need them.

Q: What’s your favorite part of your job?
A: I love solving problems, and this maps into my first true career interest, which was math. It’s not often that you can find a place where you are both able to solve a problem and see the tangible results. That’s one of the things that I like about MMIT. It would be much harder to have a significant impact as an individual at a larger company and although MMIT continues to grow, I still feel like I can move the needle in my role.

One of the other aspects that I really enjoy about the business is that we are very adaptable to change. We don’t stick to bad processes simply because that’s the way we’ve always done them. Instead, we are constantly evaluating the needs of the market and how we fit in, which makes us much more agile than the average healthcare technology organization.

Q: What do you like to do outside of work?
A: My wife gave birth to our third child less than two months ago so my current answer might be a bit jaded — SLEEP! I would say that 90% of my time outside of work is spent with my family and, as anyone with kids knows, they take up a lot of time! The other 10% is spent working out, whether it is playing tennis, running or going to the beach. We will see what this summer holds with all things considered, but I really hope to get the family down to the beach and ocean as much as possible! ♦

by Brooke McDonald

2Q Update Gives COVID Context
continued from p. 1

Of those 6.4 million, only about 950,000 likely have started receiving Medicaid benefits. With many states overwhelmed by sharp increases in unemployment claims and Medicaid applications, it will take longer for those eligible to obtain public coverage. That leaves nearly 5 million who had commercial insurance but now are going bare.

The picture is likely to change. Much is unknown about the duration of this first phase of the pandemic: how states will begin to reopen, how employers will react, how severe a second wave of infections may be, how states will adjust safety-net funding and how individuals will respond to COBRA, Medicaid and exchange offers. MMIT will continue to model changes in enrollment as new data come in.

With many states overwhelmed by sharp increases in unemployment claims and Medicaid applications, it will take longer for those eligible to obtain public coverage.

Meanwhile, COVID’s impact on market access will vary greatly by therapeutic area and brand — and will change as states begin to reopen their economies, more patients return to routine care patterns, and the insurance coverage mix continues to shift.

Pharmaceutical companies with portfolios used by younger and middle-aged patients, such as branded diabetes drugs, likely will see a greater impact than those that primarily serve older Medicare-eligible enrollees, since Medicare coverage will remain more stable during the pandemic.

Medicaid Growth Could Shrink Profits

The expected increase in Medicaid enrollment likely would result in higher Medicaid rebates paid by pharmaceutical companies compared with those paid in the commercial sector. That could lead to lower profit margins for drug companies, although the comparatively small Medicaid shift to date will mute some effects. Offsetting that, patients’ out-of-pocket costs typically are lower in Medicaid programs, likely spurring lower spending by pharmaceutical companies on patient-assistance programs and copay buy-downs.

In addition, with more Medicaid patients accessing drugs via a state Medicaid program’s preferred drug list (PDL), pharmaceutical companies also may see an increase in substitutions or denials for branded medications. That’s because Medicaid patients who wish to access a brand drug that is listed as non-preferred on a PDL almost always first must try and fail on a preferred agent. This is less common in commercial insurance, where patients typically can
access non-preferred drugs by paying a higher copay (or using a drug for which the manufacturer has given preferential pricing) without first undergoing a trial on a preferred agent.

Some uninsured patients may turn to discount drug programs for help accessing needed therapies. Many large retailers, grocery and pharmacy chains, PBMs and other entities offer such programs. For example, an Express Scripts COVID assistance website includes a link to its Inside Rx pharmacy savings program. The National Restaurant Association is promoting OptumRx’s pharmacy discount-card program, which promises average savings of 40% on all approved medications, to hard-hit business owners and staffs.

For more information on MMIT’s 2Q lives update, contact support@mmitnetwork.com.

by Jill Brown Kettler

PBM's See Solid 1Q Results Despite Challenges Ahead

Major PBMs reported strong results for the first quarter of 2020 as members rushed to fill prescriptions in March ahead of the COVID-19 pandemic. However, financial analysts warn the pandemic could have unpredictable effects on PBMs’ finances for the rest of 2020 and moving into 2021.

The 2021 PBM selling season could be disrupted in still-unknown ways, analysts said, and members are cutting back on routine physician visits and elective procedures, resulting in lower script volume overall.

Anthem, Inc., posted a particularly strong start for its new IngenioRx PBM, with earnings of $349 million, well above the $275 million to $300 million quarterly earnings that had been expected.

The impact from COVID-19 included a large spike in prescription refills during March, which helped the PBM’s performance, Anthem Executive Vice President and CFO John Gallina said in the company’s earnings conference call.

Still, investors shouldn’t expect script numbers to remain elevated, he added: “We have seen a slight drop in new scripts here in April over historical patterns.”

CVS Health Corp. reported first-quarter earnings per share (EPS) of $1.91, well above what analysts had anticipated. Citi analyst Ralph Giacobbe wrote in a May 6 investor note that the company’s Caremark PBM “put up solid results with revenue and operating profit also exceeding consensus with higher claims growth of 12.4%.” This was “aided by pull-forward of scripts due to COVID-19,” plus the partnership between CVS and Anthem on IngenioRx.

Cigna Corp.’s first-quarter adjusted EPS came in 8% above consensus, with better-than-anticipated performances in its Health Services unit, which houses PBM Express Scripts, and in its Integrated Medical segment. Health Services reported an operating profit of $1.08 billion, slightly ahead of expectations, with revenue well ahead of projections — $27.2 billion versus $25.1 billion expected, noted Giacobbe.

<table>
<thead>
<tr>
<th>Channel</th>
<th>Medical Lives</th>
<th>Pharmacy Lives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>182,150,000</td>
<td>176,210,000</td>
</tr>
<tr>
<td>Medicare*</td>
<td>48,040,000</td>
<td>48,370,000</td>
</tr>
<tr>
<td>Managed Medicaid</td>
<td>48,160,000</td>
<td>48,870,000</td>
</tr>
<tr>
<td>State Medicaid</td>
<td>13,930,000</td>
<td>14,210,000</td>
</tr>
<tr>
<td>Health Exchange</td>
<td>10,190,000</td>
<td>10,030,000</td>
</tr>
<tr>
<td>Total</td>
<td>302,470,000</td>
<td>297,700,000</td>
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</table>

*Inclusive of Medicare Administrative Contractors (MACs).
Overall, Cigna reported EPS of $3.15 on operating income of $1.8 billion, a 20% jump from the first quarter of 2019.

At UnitedHealth Group, earnings for Optum, the division that includes OptumRx, missed analysts’ expectations by about 5%, despite stronger-than-expected revenue, Jefferies equities analyst David Windley wrote in a note to investors. “OptumHealth and OptumRx both contributed to the underperformance,” which was offset by stronger-than-expected performance by OptumInsight, he said.

However, Optum reported higher-than-expected revenues, which was likely aided by the company’s acquisition of Diplomat Pharmacy Inc., Giacobbe said. Optum agreed to purchase the specialty pharmacy for $300 million in December 2019. ♦

by Jane Anderson

Use of Mental Health Medication Jumps Amid COVID-19 Outbreak
by Jinghong Chen

The COVID-19 pandemic has made a significant impact on people’s mental health, with the number of prescriptions per week for antidepressant, anti-anxiety and anti-insomnia medications going up 21.0% between Feb. 16 and March 15, according to recent research from Cigna Corp.’s Express Scripts. Despite that shorter-term trend, the PBM found that overall use of both anti-anxiety and anti-insomnia medications declined over the past five years. Antidepressant use climbed 15% from 2015 to 2019, with teens seeing the greatest utilization increase (38.3%) during that time.

Payers’ Use of Copayment Accumulators Is Growing

by Angela Maas

In a reverse course from its stance a year ago, CMS recently finalized a rule allowing nongrandfathered individual and group market plans to not count manufacturer copayment assistance toward members’ annual deductible and out-of-pocket responsibilities. Known as copay accumulators, the programs began appearing on the pharmaceutical industry’s radar a couple of years ago — and Zitter Insights research reveals their popularity is showing no sign of slowing.

Traditionally, when a manufacturer provides copay assistance for one of its drugs, that dollar amount would count toward the patient’s deductible and out-of-pocket maximum. Once people hit their annual limit, their insurer picks up their prescription costs for the rest of the year. But copay accumulator programs prevent those manufacturer-provided funds from applying to the deductible and out-of-pocket max. Instead, when members have used all of the copay assistance available to them, their payments then start counting toward their deductible and out-of-pocket costs.

Many copayment assistance programs offered by pharmaceutical companies have helped patients, particularly those on costly specialty medications, stay adherent to their treatment regimens. But many payers have pushed back against these programs, contending that the offerings undermine their benefit designs.

For the Managed Care Biologics and Injectables Index: Q1 2020, Zitter polled 50 commercial payers with 131.8 million covered lives from March 4, 2020, to April 2, 2020, about their use of copay accumulators. Payers with more than 50% of the covered lives said they had already put such a program in place in 2019 (see chart below). That’s compared with 16% of 149.1 million covered lives from 48 payers with the same response last year.

AIS Health and Zitter are both owned by MMIT.

When asked if they were differentiating the programs by therapeutic area, 48% of 97.9 million covered lives from 29 payers in 2019 said no. This year, among 31 payers representing 101.6 million covered lives, payers with 96% of those covered lives said they were not differentiating.

For more information on the Zitter data, contact Jill Brown Kettler at jbrown@aishealth.com.

Over 50% of payers have already implemented a copay accumulator program in 2020, which has more than tripled since last year

<table>
<thead>
<tr>
<th>Year</th>
<th>Already implemented in previous year</th>
<th>Planning on implementing in current year</th>
<th>Not planning on implementing</th>
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</thead>
<tbody>
<tr>
<td>2019</td>
<td>16%</td>
<td>26%</td>
<td>23%</td>
</tr>
<tr>
<td>2020</td>
<td>52%</td>
<td>11%</td>
<td>14%</td>
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Payers’ Adoption of Copay Accumulator Programs

“A copay accumulator program, which may also be known as an ‘Accumulator Adjustment’ or ‘Variable Copay’ program, is a program designed to lower plan sponsor drug expenditures. We are referring here to a program in which the manufacturer copay assistance would not be counted towards patients’ deductibles for the plan year.”

<table>
<thead>
<tr>
<th>Payer Name</th>
<th>Payers’ Current Administration of Copay Accumulator Program</th>
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<tbody>
<tr>
<td>Express Scripts PBM</td>
<td>“We administer it through our own in-house Specialty pharmacy for any and all biologics and/or oncology products. Clients sign up for participation in this program.”</td>
</tr>
<tr>
<td>CVS Caremark</td>
<td>“Traditional approach in terms of accumulor program management and the application of not including copayment assistance towards deductible.”</td>
</tr>
<tr>
<td>Aetna, Inc.</td>
<td>“Clients can opt into a benefit design where copay cards are maximized and any amount picked up by the copay card does not count toward patient out of pocket.”</td>
</tr>
</tbody>
</table>

Coverage

Pharmacy Benefit
Under the pharmacy benefit, about 55% of the lives under commercial formularies are covered with utilization management restrictions. Almost 35% of the lives under Medicare Part D formularies are not covered for at least one of the drugs.

Medical Benefit
Under the medical benefit, about 57% of the lives under commercial policies are covered with utilization management restrictions. Meanwhile, almost 78% of the lives under Medicare Part B policies have access to at least one of the drugs without utilization management restrictions.

DATA CURRENT AS OF Q2 2020
Trends

Roxadustat Shows Efficacy

In November 2019, AstraZeneca said its FibroGen-partnered drug roxadustat, an oral first-in-class drug to treat anemia in patients with chronic kidney disease, demonstrated positive results in its Phase III trial. The trial showed that the treatment increased hemoglobin levels versus placebo and epoetin alfa.

Via PharmaTimes

Roxadustat May Gain FDA Approval in 2020

In anemia associated with chronic kidney disease, “hypoxia inducible factor (HIF) stabilizers are a new class of oral agents in development,” says Mesfin Tegenu, R.Ph., president of PerformRx, LLC. “One of these agents, roxadustat [from FibroGen, Inc.], could see FDA approval, and Phase III trial results are expected for several other candidates in this class in 2020.”

Subscribers to AIS’s Specialty Pharmacy may read the in-depth article online

FDA Expanded Label for Mircera

In June 2018, the FDA expanded the label for Mircera (methoxy polyethylene glycol-epoetin beta) to include the treatment of pediatric patients 5 to 17 years old with chronic kidney disease (CKD)-related anemia who are on hemodialysis and are switching from another erythropoiesis stimulating agent after stabilization of their hemoglobin level. GoodRx lists the price of five 50 mcg syringes as more than $450.

Subscribers to AIS’s Specialty Pharmacy may read the in-depth article online
Key Findings

Reality Check: Anemia — Chronic Kidney Disease

Market Events Drive Changes

In June 2018, the FDA expanded the label for Mircera (methoxy polyethylene glycol-epoetin beta), a Roche drug that is commercialized in the U.S. and Puerto Rico by Vifor Pharma Inc, to include the treatment of pediatric patients 5 to 17 years old with chronic kidney disease (CKD)-related anemia who are on hemodialysis and are switching from another erythropoiesis stimulating agent (ESA) after stabilization of their hemoglobin level. In May 2018, the agency approved the first epoetin alfa biosimilar, Pfizer Inc.’s Retacrit (epoetin alfa-epbx), for the treatment of anemia caused by CKD, among other indications.

Competitive Market Landscape

Contracting is common for preferred status, and patients may have to try and fail a preferred product first.

Pharmacy and Medical Implications

Most payers cover the drugs under both the pharmacy and medical benefits. Most policies require diagnosis of anemia due to CKD. Most policies require documented hemoglobin levels be less than 10mg/dL to initiate ESA therapy. Some payers require a step through the preferred product. Most plans require dosing adjustments based on hemoglobin levels. Specialty pharmacy dispensing is common.

DATA CURRENT AS OF Q2 2020
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.


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.