MMIT RADAR

Spotlight on Market Access

Actionable understandings from AIS Health's in-depth coverage

May 18, 2020

COVID-19 Is Causing Changes to Models, Entities Throughout Health Care Landscape

While much of the focus on the health care system understandably has been on hospitals and pharma during the COVID-19 pandemic, other industry stakeholders also have a role to play. And as telehealth grows and entities such as home infusion providers and retail pharmacies adapt in order to continue providing their services, many of the changes likely will remain in place — and potentially ripple through the system, for better or for worse.

With many people hesitant to go out in public, particularly to physician offices and hospitals, in-person doctor visits have gone down while telemedicine has increased. CMS and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) have made a series of moves to expand telehealth services, relax some requirements around them and ensure providers are reimbursed for these services during the pandemic. Medicaid programs and commercial insurers also have taken similar steps. In addition, points out Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates, "medical boards have adopted special policies for telemedicine, but it is not clear which, if any, will remain after the pandemic subsides."

continued on p. 4

Prime Studies Show High Costs Among Asthma, Hereditary Angioedema Biologics

Prime Therapeutics LLC recently released the results of two studies focused on two classes of high-cost biologics, asthma and hereditary angioedema (HAE). Both conditions have seen new therapies recently and may be candidates for value-based contracts.

While more than 25 million people in the United States suffer from asthma, about 5% to 10% of those suffer from severe allergic or eosinophilic asthma. While asthma overall has a societal cost of around $56 billion, those patients account for almost 50% of that cost. Global Initiative for Asthma 2019 guidelines recommend an asthma biologic for this subset of patients, and the first Prime study examined the use of five biologics: Cinqair (reslizumab), Dupixent (dupilumab), Fasenra (benralizumab), Nucala (mepolizumab) and Xolair (omalizumab).

The study authors cite the Institute for Clinical and Economic Review's (ICER) 2018 final report on asthma, which concludes that all five drugs "exceed commonly accepted thresholds for cost-effectiveness," and that the fair price to value was between $6,500 and $10,100 annually.

Researchers analyzed integrated pharmacy and medical claims from 14 million commercially insured members from January 2017 through June 2019 to identify claims for the five biologics that were specific to asthma in order to determine utilization trend and spend.

To determine persistence, pre/post total cost of care and asthma-related events among new starts, researchers examined pharmacy and medical claims data from July 2017 to December 2018 for four of the biologics. Dupixent was not included because the FDA did not approve it for use in asthma until October 2018.

Members were required to be continuously enrolled 182 days both pre-period their earliest asthma biologic claim and post-period 182 days from that date. Researchers evaluated drug persistence at days 90 and 182 after members' index date. For the 90-day post-period mark, persistence was defined as three or more claims, and for the 182-day post-period, persistence — which was based on prescribing information — was at least four claims for Fasenra and at least six for Cinqair, Nucala and Xolair.

Use of Asthma Biologics Increased 78%

The first analysis found that the use of asthma biologics increased 78% over two-and-a-half years, from 3.3 utilizers per 10,000 members in first-quarter 2017 to 5.8 utilizers in the second quarter of 2019. During that period of time, per-member per-month costs for the drugs rose 85%.

In the second assessment, researchers found 1,492 members who were new starts between July 2017 and December 2018. Thirty of them started on Cinqair, 84 on Fasenra, 432 on Nucala and 946 on Xolair.

Three months after the index date, most persistence was seen in members taking Cinqair, at 86.7%. Fasenra users had the lowest rate, at 59.5%. Overall persistence was 73.5%. At the six-month mark, Cinqair users were most persistent, at 70.0%, while Xolair users were least persistent, at 49.5%. Overall persistence was 51.5%.

Among users who suffered an asthma-related hospitalization and/or emergency room visit, the percentage of persistence was 3.2% in the pre-period and 1.6% in the post-period.

The average total cost of care per member in the pre-period was $10,913, but in the post-period, that increased to $28,233. Biologics were responsible for 95% of the cost increase, researchers found. In addition, "total medical costs did not decline considerably to offset the substantial asthma biologic costs, dispelling the conventional wisdom that these agents decrease total health care costs in the first six months of treatment," says Catherine Starner, Pharm.D., health outcomes consultant senior principal at Prime and study co-author. "Asthma-related medical event rates decreased 1.6% after asthma biologic initiation; this translates into a number needed to treat of 62 members to prevent one asthma-related medical event, which is a substantial asthma biologic drug cost investment to prevent one event."

Multiple Events May Have Led to Rise

Asked about the 78% rise in use over two-and-a-half years, Starner tells AIS Health that Fasenra was approved for severe asthma in November 2017 and Dupixent in October 2018, "resulting in increased utilization and spend in the asthma biologic category." Then in 2019, the Global Initiative for Asthma "provided clear direction on how to use biologic agents for the treatment of severe asthma. It is also possible that providers were becoming more comfortable prescribing asthma biologics during our analysis."

She cautions that "direct comparisons between products should not be made, and statistical testing comparing the persistence between products was not performed." She recommends that payers assess all of the biologics for value-based contracts with manufacturers. "In terms of making formulary decisions, factors other than persistence should be considered, such as comparative clinical effectiveness, safety and tolerability, and convenience to patients."

To improve persistence, help members and providers "make better decisions about their medications" and help identify members whose asthma is untreated, Prime offers its GuidedHealth clinical programs. "Through the analysis of pharmacy and medical data, actionable clinical intelligence is provided to prescribers, members and health plans," Starner says. "These insights can result in improved care, safer medicine use, better outcomes and lower overall cost of care."

According to Starner, "a substantial increase in total cost of care, poor persistence and a small decrease in hospitalization/ER visits after asthma biologic therapy initiation…provide further evidence for insurers to consider implementing value-based agreements to ensure fair pricing to value and clinical programs to improve persistence."

"These types of analyses assessing total health care cost help improve our understanding of how to optimize our scarce health care resource dollars and improve the quality of medication use among our members," she says.

Study Analyzed Haegarda, Takhzyro

The other study focused on HAE, a rare disease that causes episodes of subcutaneous or submucosal edema. Therapies to treat it consist of on-demand treatments for acute episodes and prophylactic drugs for long-term use to prevent attacks. The latter category has three treatments available: Cinryze (C1 esterase inhibitor), which the FDA approved in 2008; Haegarda (C1 esterase inhibitor), with a 2017 FDA approval; and Takhzyro (lanadelumab-flyo), approved in 2018.

Study authors noted that an ICER review concluded that the prophylactic drugs "had incremental cost-effectiveness ratios above the commonly accepted willingness-to-pay threshold of $150,000 per quality-adjusted life year, but 'results of the models were very sensitive to baseline attack rates, prophylactic and on-demand drug costs, and treatment effect estimates.'"

The Prime study was looking to find real-world treatment costs of the newest prophylactic drugs to assist in formulary decisions, cost-effectiveness comparisons and negotiations for value-based contracts. Researchers analyzed 15 million commercially insured members with integrated pharmacy and medical claims who had newly started on either Haegarda or Takhzyro before Feb. 1, 2019, with continuous eligibility for 180 days after their first claim.

While Cinryze is infused, so it's frequently billed through the medical benefit, the other two drugs are self-administered and billed through the pharmacy benefit, so Prime selected those to study, says Patrick Gleason, Pharm.D., assistant vice president of health outcomes at Prime.

Researchers identified 85 members with a first claim for Haegarda and 50 with a first claim for Takhzyro before Feb. 1, 2019, and 29 within each group met additional criteria.

Prophylaxis Was More Than $225,000

The cost of prophylactic treatment for 180 days was a mean of $226,989 for Haegarda and $278,267 for Takhzyro. Among Haegarda users, 62.1% had a claim for an on-demand agent, while 65.5% did among Takhzyro users. The mean cost for on-demand therapy for 180 days was $108,025 for Haegarda users compared with $82,591 for Takhzyro.

Asked about the most interesting findings, Gleason notes that HAE therapy "is extremely expensive." He says that the variance in prophylactic treatment for Haegarda is "likely due [to] its weight-based dosing, where the Takhzyro is fixed dosing. We saw less per member treated Takhzyro cost variance."

In addition, "while about a third of these members starting Haegarda or Takhzyro had zero on-demand (acute) HAE drug therapy, some members had on-demand HAE drug therapy costs well over $100,000. We need to further investigate why some members had on-demand HAE treatment costs in the $100,000s while on prophylactic therapy. If it is due to prophylactic therapy failure, we'd like to negotiate a value-based contract to recoup the failed prophylactic therapy cost."

He says researchers "did not randomize the members to therapy, and we do not know if the members' HAE illness severity was the same. We do see about the same number of members had zero on-demand HAE

drug cost during their first six months of prophylactic therapy: 11 of 29 Haegarda and 10 of 29 Takhzyro members."

As far as criteria that could be used for value-based contracts and preferencing of the drugs, "because Prime has access to both medical and pharmacy claims data, total cost of care contracts are the outcome measure we like to target," Gleason tells AIS Health. "There are many arrangement options, and it may depend on the drug and manufacturer."

"Our drug super spender predictive modeling output allows our specialty drug managed care pharmacists to be informed early when a member has the potential to become a drug super spender."

According to Gleason, "using integrated medical and pharmacy claims to evaluate total cost of care is critical to revealing the full story of member behavior and costs, so having a PBM partner that can provide that is key. This comprehensive information is also helpful when informing cost-effectiveness models to understand real-world cost variance for weight-based dosing drugs like Haegarda and comparing that to real-world costs of fixed-dosed Takhzyro."

Prime, he says, uses the integrated pharmacy and medical benefits of extremely expensive therapies that can result in "drug super spender members" to build predictive modeling. "Our drug super spender predictive modeling output allows our specialty drug managed care pharmacists to be informed early when a member has the potential to become a drug super spender. Early notice can lead to drug therapy optimization and care management services provided at the most crucial time, early in therapy."

Contact Gleason and Starner through Denise Lecher at denise.lecher@primetherapeutics.com. ✧

by Angela Maas

This story was reprinted from AIS Health's monthly publication RADAR on Specialty Pharmacy. *Visit https://aishealth.com/product/specialty-pharmacy.*

COVID Prompts Multiple Changes

continued from p. 1

"This has been a tipping point for telehealth," maintains Steven F. Robins, managing partner and principal at The New England Consulting Group. "Thousands of people who would have been resistant have now tried it. There are diagnostic products ranging from vision care refracting to skin disease AI that are already good and will get great, further driving telehealth utilization."

The Deloitte Center for Health Solutions and the American Telemedicine Association surveyed health care executives in November 2019 through January 2020 on virtual health's likely impact on the health care landscape over the next 20 years. While the surveys were conducted before a pandemic was declared, the company contends that some of the findings, which were published at the end of April, are relevant to COVID-19:

- ***"Digital tools are enabling early detection***: A key challenge in the United States and elsewhere has been the ability to quickly identify and test people who might have been exposed to the virus. China quickly deployed an app and other sensors that [monitor] body temperatures."
- ***"Virtual visits are helping to support and triage patients***: Early lessons are showing that virtual health can support the demand for medical support when it is advisable for most people to stay at home....For people who don't need to leave their homes because they are having medical issues or appointments unrelated to the virus, they can protect themselves and others in their communities and still get the care they need. Even those with the virus — if their symptoms are mild — can most often be treated at home."
- ***"Convenient, accessible care and home-based testing***: Drive-through testing labs are helping local communities get a handle on the spread of contagion while enabling people to avoid hospitals and close contact with others. We could also see more widespread home-based testing in the future. Today, consumers already have the ability to test themselves for a wide range

of potential health problems, from strep throat to urinary tract infections. In the future, home-based tests for a new virus might be developed quickly and distributed to people or communities at risk."

According to the IQVIA Institute for Human Data Science, in-person provider appointments have decreased by approximately 70% to 80% from a baseline of about 100 million visits per month nationwide. In its new report released in May, titled *Shifts in Healthcare Demand, Delivery and Care During the COVID-19 Era: Tracking the Impact in the United States*, the firm points out that certain specialties may be more inclined to use telemedicine (see chart, p. 7).

Per the report, "in the baseline period, claims for telemedicine were less than 1% of claims, and while usage has climbed dramatically, use of virtual patient engagement has not offset the declines in office visits."

Rubinstein says that if telehealth reimbursement and remaining face-to-face patient appointments are not sufficient to sustain provider offices as far as office space and staffing, "while that would be bad for affected nurses, [physician assistants] and support staff, it is not clear that it would be bad for patient care or for the health care system."

Decline in Lab Tests Has Occurred

An increase in telehealth "may decrease the use of diagnostic testing procedures because of the inconvenience," says Lee Newcomer, M.D., principal at Lee N. Newcomer Consulting LLC. "Physicians will rely more on history, symptoms and observation to determine if an issue requires further evaluation."

Indeed, the IQVIA report finds that there has been a sharp decline in lab tests across all sites of care, which "will likely lead to delayed treatments and potentially increased costs in the future."

"Providers will be suffering from decreased revenues," says Newcomer. "Most of medicine is not urgent, and a lot of therapies have been delayed or canceled. While I do think that consumers will once again become patients, the return will be slower and initially limited to acute problems. I am concerned that we will experience a surge of more advanced cancer diagnoses or other infectious diseases because of deferred vaccinations, for example. There will be a need to triage any surge that occurs as the lockdowns expire. I am concerned that the first to call will be the first to get scheduled regardless of the seriousness of the illness."

"COVID-19 will absolutely transform telehealth and telemedicine."

"COVID-19 will absolutely transform telehealth and telemedicine," states Lisa Kennedy, Ph.D., chief economist and managing principal at Innopiphany LLC. She tells AIS Health that while "telemedicine is a great option for certain groups of patients that are short on time or require care that a physician could give without having to see/examine the patient,…it isn't the answer for everything, so being able to identity and triage care through telemedicine might be the first step. In parts of the UK, you call a service whereby a physician calls you back in 30 minutes, and then they can direct you to a hospital or care center, and equally they can tell you the time to wait. They can also give guidance and reassurance to the patient. That's great telemedicine."

"COVID-19, followed by the CARES Act, could be the catalyst that helped spark broader use of telehealth," says Ashraf Shehata, KPMG national sector leader for Healthcare & Life Sciences. He notes that prior to the pandemic, "telehealth was seen as an instrument in value-based care programs to help better manage costs. The use of telehealth during the pandemic can provide a test that examines whether telehealth can help reduce costs and offer comparable outcomes."

"Some of the immediate uptick in telehealth is expected to be retained but not all of it," says Murray Aitken, senior vice president, IQVIA, and executive director, IQVIA Institute for Human Data Science. "The learnings related to where and how it works best will likely be a guide. Short-term impetus to stay in touch with some patients has trumped concerns about telehealth or even litigation, but longer term there will likely be a shift back towards the old model. Survey results suggest that double the old level is likely, but that may be based also on provider expectations of continued payer reimbursement."

With many states still under stay-at-home orders, and people hesitant to visit outside their homes, home infusion is more important than ever.

"If you can do infusion at home, you need to do it there," maintains Shehata. "This is about controlling infection risk in the near term, and many home infusion candidates are in a high-risk category. Longer term, there has been a shift toward delivering care in the most economical and clinically appropriate setting, largely driven by payers."

"We have seen an increase in some home infusion utilization of select therapies in certain markets where patient administration sites of care are shifting from the acute care or hospital outpatient setting to the home, related to the pandemic," says Drew Walk, CEO of Soleo Health. "We have also seen a significant reduction in other therapies due to the postponement of non-COVID-related procedures in health systems and provider offices."

"If you can do infusion at home, you need to do it there."

Walk tells AIS Health that while the types of drugs being administered at home have been fairly consistent with what were administered before the pandemic, he's seen "a broader opportunity to provide first dosing in the home, which may have been offered only in a controlled setting previously."

"Antibiotics/antivirals, pain management, total parenteral nutrition and [intravenous immune globulin] are currently the most common treatments given through home infusion," says Shehata, adding that other therapies may be administered at home, but "that depends upon the circumstances, such as the medication and the risk to the patient."

Newcomer says a shift to home infusion "will be relatively small" and would be done for two main reasons: avoiding exposure to people who may be infected and bringing down the overhead cost of hospitals or clinics. "The shift is limited by the small number of medications that don't require physician proximity for side effect management," he says.

Option Care Health, Inc., has moved some of its services to a virtual setting, including "remote triaging, patient education and teaching, nurse oversight and assistance to discharge planners and patients," says Harriet Booker, chief operating officer of the company. It also has reallocated some of its 2,900 infusion nurses and pharmacy clinicians to places with the greatest need, such as New York, New Jersey and Connecticut.

Shift to Home Already Has Started

Some plans already have been shifting administration of certain therapies to patient homes and provider offices, which are more cost-effective settings than hospitals, points out Rubinstein. The 10th edition of Magellan Rx Management's *Medical Pharmacy Trend Report* found that among 54 payer respondents, 39% had a mandatory site-of-service program in place in 2019. Among the members shifted into such a program, 34% were shifted into the home infusion setting.

"There could be more home infusion, with drugs that pose low risk of serious adverse events during or immediately after infusion or where a patient tolerated prior infusions of these drugs with no or minimal difficulty," says Rubinstein. "With respect to patients receiving chemotherapy, a move to home infusion would require a way to manage performance and evaluation of laboratory tests to assess the safety and appropriateness of the intended drug therapy, and a decision prior to infusion to change dosage, change drugs, go ahead or hold off."

Kennedy points out that while CMS has changed its policies in support of home infusion, "not everyone is on board." She notes that the Community Oncology Alliance "has raised safety concerns about home infusion centered on a lack of training of those in the community administering treatment at home versus trained oncology nurses."

Conversely, the National Home Infusion Association "is strongly supportive of home infusion as a viable option for keeping patients safe," says Kennedy. She also points out that guidelines from the American Society of Clinical Oncology (ASCO) say that providers should "consider whether home infusion of chemotherapy drugs is medically and logistically feasible for the patient, medical team and caregivers."

In these guidelines, she says, "ASCO raises the key challenge here, which is how to take a system, process and resource designed to be administered in one setting and then move it to a home setting. It may not be feasible because of training of new staff, available resources, travel constraints, insurance and other logistics that mean that it just can't be scaled properly. So it really depends on the situation, geography and capability of the center."

"Going forward there will be a lot of candidates for home infusion, and some customers/patients may like the convenience of getting care at home," says Shehata. Investor respondents to the survey on which the *2020 KPMG Healthcare and Life Sciences Investment Outlook* was based "saw a good opportunity in home health care, and that survey was taken before COVID-19. The burden on health systems is going to test new care models and open up more possibilities tied to home health care, including infusion."

"The use of home infusion will also depend upon the nature of the medications used and the amount of time it takes to infuse the drug — anywhere from a half hour to four hours — and any specific handling requirements," Shehata says. "There might be opportunities for alternative care models to be introduced here. The ability for nurses to teach patients how to self-administer the medicines is an important facet to this.

"However, some patients undergoing infusions of certain medications need to have vital signs tracked and need monitoring for adverse reactions," he continues. "One option is to use telehealth with telemetry to remotely track a patient's vital signs to ensure that patients are not suffering from adverse events while undergoing infusion. Another option is the nurse administering the drug can also leave the patient with a cell phone to call if there is any problem with a medication that requires several hours of infusion time. The response time has to be acceptable, and clinical risk has to be appropriate in these matters."

According to Robins, while most infusions will still be administered in traditional sites such as hospitals and outpatient clinics, "there will be an evolution toward moving a number of chronic treatments to the home," including dialysis, a shift that he says already

Physician Interactions in Week Ending April 3, 2020

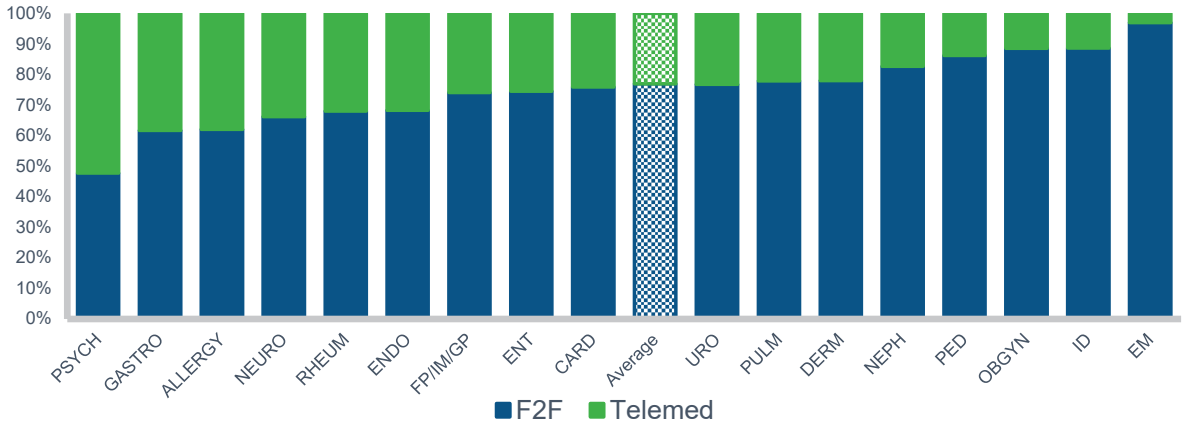

Exhibit notes: F2F = face to face visits; Telemed = telemedicine; Psych = psychiatry; Gastro = gastroenterology; Neuro = neurology; Rheum = rheumatology; FP/IM/GP = family practitioner/internal medicine/general practitioner; Ent = ear/nose/throat; Card = cardiology; Uro = urology; Pulm = pulmonology; Derm = dermatology; NEPH = nephrology; Ped = pediatrics; Ob/Gyn = obstetrics/gynecology; ID = infectious disease; EM = emergency medicine

SOURCE: IQVIA Institute for Human Data Science, *Shifts in Healthcare Demand, Delivery and Care During the COVID-19 Era: Tracking the Impact in the United States,* released May 2020. From IQVIA real-world data, medical claims, April 17, 2020, reporting week ending April 3, 2020. Download the report at www.iqvia.com/insights/the-iqvia-institute.

was occurring before the pandemic. "In order for this shift to be significant, however, there will need to be improvements across the integration of smart technologies, including HIPAA-compliant integration of remote equipment and patient monitoring. It is important to remember that during the COVID 19 crisis, some of these requirements have been relaxed."

Robins tells AIS Health that "we also expect to see a number of diagnostic procedures that are conducted by labs or in providers' offices move into the home setting. This will result from a combination of emerging technologies integrated with smartphones, as well as providers starting to offer in-home options like mobile imaging stations that can be easily cleaned as they move from patient home to patient home."

"The outpatient or infusion center-based model is great, but it is going to need multiple approaches tied to the complexity of treatment and also the consistency of treatment. The problem is that the current model is based on convenience for the health system," asserts Shehata. "This could require some changes in the pharmaceutical supply chain to have the medications delivered at home rather than the infusion center or hospital, but a number of specialty pharmacies manage this process. Home delivery also can help patients who have transportation issues. Having care delivered at the home may also have the net effect of improving medication adherence."

Pharmacy Models May Change

Pharmacies have been offering home delivery of prescriptions, and the pandemic has only increased this practice. "Home delivery was already increasing before the crisis, and, on a limited basis, pharma companies were testing subsidizing these costs as a way of increasing adherence and improving outcomes," points out Robins.

"COVID has accelerated the adoption of this [home delivery] model by existing pharmacies, and we would expect that consumers will like this new option and take advantage of it as part of a 'new normal,'" says George Van Antwerp, managing director at Deloitte Consulting, LLP. However, one potential roadblock may be that "the economics aren't viable for most prescriptions," says Newcomer.

Some pharmacies, such as CVS, have been offering free delivery during the pandemic. "I do not know whether retail pharmacies that have added it on a temporary basis will continue to offer free home delivery of prescription drugs once the pandemic subsides," says Rubinstein. "On the other hand, this is the way that mail-order pharmacies do business, so why not extend the same to retail pharmacy?"

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Shehata notes that "some pharmacies that are integrated with health benefits are using home delivery to their advantage. For example, patients covered by Aetna received from their CVS pharmacy a COVID-19 'care package' shortly after the diagnosis is made. Now the PBM can become a broader fulfillment operation for patient needs if they want to carry this further and into different diagnoses."

Rubinstein agrees. "If customers like this mail-order service and choose to continue it after the pandemic subsides, it would be most efficient for CVS retail to fulfill those prescriptions through the CVS mail-order facility," he maintains. "This could, in turn, impact retail pharmacy volume: If there is now just one pharmacist on duty, that cannot change while the pharmacy is open, but technician staffing levels can be adjusted per expected prescription volume."

Some pharmacies have converted to drive-thru service only, and many are offering curbside pickup.

"COVID-19 may require the retail pharmacy to flip how they traditionally operate," says Shehata, which is the pharmacy in the back and other products toward the front, allowing customers to pick up other items on the way to getting their prescriptions. "The drive-thru now needs to be adapted so the customer can pick up anything from the store through the drive-thru window. This requires a lot of integration between the e-commerce site and what inventory is available in local pharmacies. Some grocery chains with pharmacies are using curbside pickup, and that can be arranged for medicines if a person shows their ID to the person han-

dling the delivery. If non-health care retail can adapt this quickly with curbside pickup, the pharmacy chains need to adapt immediately."

A challenge, though is that "drive-thru is interesting but requires reconfiguration and construction of space, much like the fast food restaurants have done," points out Rubinstein. "Traditionally configured retail pharmacies in office buildings and in shopping malls may not be able to do this."

"Nobody's building new drive-thrus, but if they exist, people may prefer them for a time," says Aitken. "Longer-term home delivery by pharmacies is unlikely, beyond pre-COVID levels and mail-order activity."

"Undoubtedly there will be more drive-thru and prescription pickup," maintains Kennedy. "All the individuals who need these medications will need to be particularly cautious to continue to self-isolate and that includes how they pick up their medications, so they will naturally gravitate to remote solutions for including mail order and drive-thru. Pharmacies looking to keep this business and keep their customers safe will need to quickly innovate new solutions to help their customers."

"COVID-19 may require the retail pharmacy to flip how they traditionally operate."

Van Antwerp agrees. "Depending on the length of the pandemic and potential future waves, drive-thru and other models will likely become more normal as consumers and companies look at how to best serve their customers while maintaining safe, physical distancing."

With all the shifts in sites of care, will the pandemic result in some kind of new entity where people can receive treatment?

Newcomer says he "think[s] it is unlikely. COVID-19 will be a permanent issue. It will require different protocols within existing facilities, but I don't anticipate the creation of new entities to avoid it entirely because the virus is universal."

But according to Robins, "multiple new business and service models will come into being as IDNs [i.e., integrated delivery networks], chain drug stores, payers, technology companies, legislators, patients and others all look for safe, convenient, cost-efficient ways to source health care."

Kennedy advises that "a place to look toward would be DaVita-like centers that are highly specialized in the care and separation of ESRD [i.e., end-stage renal disease] patients. This might be an interesting analog for other areas."

"A lot of these new entities are able to come into being with technology enablement that connects caregivers and patients."

Shehata tells AIS Health that "we are seeing some of that now. The CARES Act has changed medical credentialing and opened more avenues for telehealth. COVID-19 is requiring health care providers to think of new care models to contain the exposure risk to patients. So we might see more avenues that merge telehealth, home health, outpatient treatment and acute care. Some of this may change when we get to the 'new normal,' but care models that work are likely to be extended if they are convenient or cost less. A lot of these new entities are able to come into being with technology enablement that connects caregivers and patients."

View the Deloitte findings at https://bit.ly/3dGw6ew, and download the IQVIA report at www.iqvia.com/insights/the-iqvia-institute.

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by Angela Maas

Reality Check: **Multiple Sclerosis**

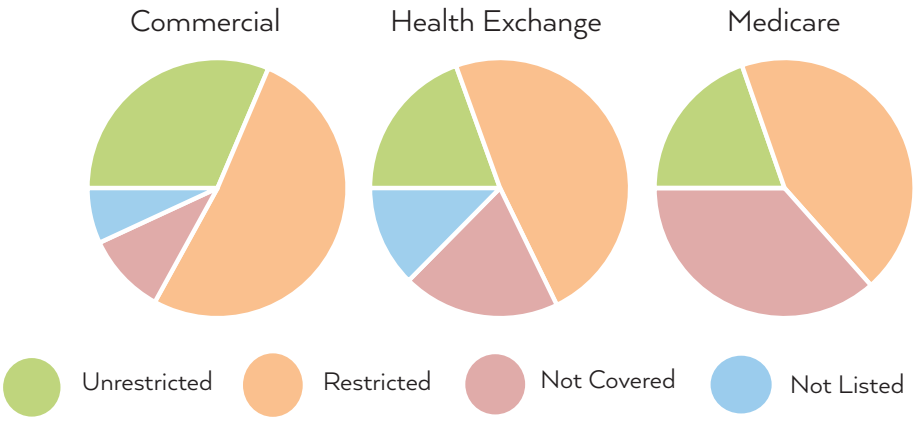
Our Point of View

The multiple sclerosis (MS) space continues to be a crowded one, with three new disease-modifying therapies (DMTs) launching in 2019. In October, the FDA approved Biogen Inc. and Alkermes plc's Vumerity (diroximel fumarate) for the treatment of relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. In March, the FDA approved Novartis Pharmaceuticals Corp.'s Mayzent (siponimod) and Mavenclad (cladribine) from EMD Serono, Inc., a Merck KGaA subsidiary. Both are indicated to treat adults with relapsing forms of MS. Early and ongoing DMT therapy is the standard of care for MS. While the condition has no cure, DMTs can prevent or delay disease progression and disability.

Coverage

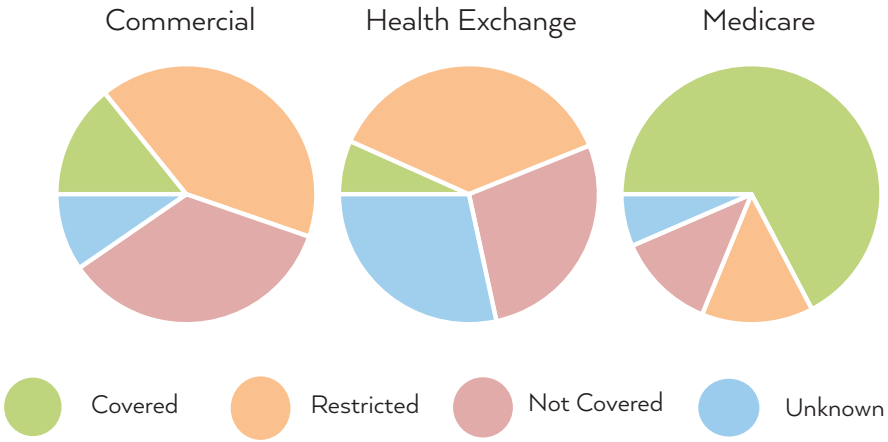
Pharmacy Benefit

Under the pharmacy benefit, about half of the lives under commercial formularies are covered with utilization management restrictions. Around 37% 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 41% of the lives under commercial policies are covered with utilization management restrictions. Almost 67% 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 Q1 2020

Reality Check: **Multiple Sclerosis**

AIS Health's View

DMTs remain one of the highest-spend drug classes for payers, according to a study published in *Neurology*, with prices rising yearly at rates five to seven times higher than prescription drug inflation. 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 tells AIS Health that "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."

Trends From AIS Health

FDA Approves Vumerity


RADAR on Specialty Pharmacy
May 2018
Administration Unveils Blueprint Aimed at High Drug Prices
Second Guidance 2020 Deadline Has Impact Beyond Pharma

In October 2019, the FDA approved Biogen Inc. and Alkermes plc's Vumerity (diroximel fumarate) for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. The agency approved the capsule through a new drug application under the 505(b)(2) pathway, with reference drug Tecfidera (dimethyl fumarate) from Biogen. The companies priced the drug at $88,000 per year.

Subscribers to AIS's *RADAR on Specialty Pharmacy* may read the in-depth article online

As Treatment Options Expand, So Do Costs


RADAR on Drug Benefits
May 25, 2018
Express Scripts Inks Deal to Improve Prolonist Price, Access
To Boost Medication Adherence, 'Think Outside the Box'

FDA's approval of Vumerity made it the third oral disease-modifying therapy (DMT) approved in 2019 to treat relapsing forms of multiple sclerosis, the most common type. With prices rising yearly at rates five to seven times higher than prescription drug inflation, according to a study published in Neurology, DMTs remain one of the highest-spend drug classes for payers.

Subscribers to AIS's *RADAR on Drug Benefits* may read the in-depth article online

FDA Approves Generic Gilenya


RADAR on Specialty Pharmacy
May 2018
Administration Unveils Blueprint Aimed at High Drug Prices
Second Guidance 2020 Deadline Has Impact Beyond Pharma

In December 2020, the FDA approved HEC Pharm Co. Ltd.'s, Biocon Ltd.'s and Sun Pharmaceutical Industries Ltd.'s fingolimod for the treatment of adults with relapsing forms of multiple sclerosis. The capsules are the first generic versions of Novartis' Gilenya (fingolimod) capsule that the agency has approved. The drugs' launch dates are unknown following a U.S. district judge's barring the generics' launch in June via a temporary injunction requested by Novartis in its patent case against a variety of manufacturers.

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Key Findings

Competitive Market Landscape

Contracting is prevalent among the interferons, where formulary preference drives choice. The orals are all different molecules. Contracting is expected to occur for these drugs but not to compete against the other brands. Competitive contracting on all the monoclonal antibodies (MABs) except Tysabri is also expected.

Medical and Pharmacy Benefit Implications

Interferons and Copaxone, as well as its generics, are considered first line in the treatment pathway. There are no true generics for the interferons. But with Copaxone generics, including Glatopa, available, some plans require those to be used. Interferons, Copaxones and orals are generally covered under the pharmacy benefit, although some coverage is seen for interferons under the medical benefit. MABs can be covered under both benefits, while infusible MABs appear most often on the medical benefit policies. All drugs for this indication are considered specialty drugs.

AIS Health's View

Nonadherence to DMT therapy remains a top cost driver, says Gail Bridges, Pharm.D., director, specialty clinical products for Accredo. "Despite nonadherence potentially leading to exacerbations and potentially permanent neurologic consequences, more than 25% of MS patients discontinue therapy within the first three months." Engagement with patients to proactively identify and resolve barriers to access is essential to achieving optimal therapeutic outcomes, she tells AIS Health. 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 says.

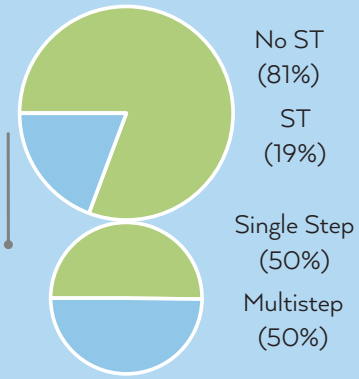
Characteristics

Indication

Multiple Sclerosis

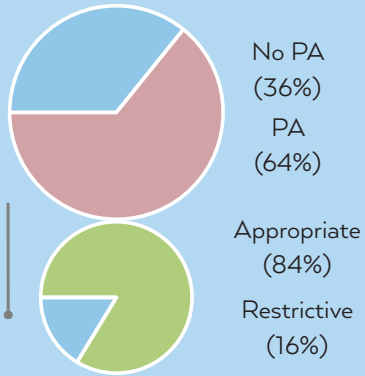
Step-Therapy (ST) Policies

A review of ST policies for payer-controlled formularies:



Prior-Authorization (PA) Policies

A review of PA policies for payer-controlled formularies:



DATA CURRENT AS OF Q1 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.

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.

MMIT has been 100% focused on market access for decades. We combine deep domain expertise around drug coverage with innovative technology and trusted data to answer key business questions related to access. MMIT data is trusted by U.S. physicians and sourced through a combination of direct partnerships with payers and PBMs and a technology infrastructure that is powered by smart business logic, artificial intelligence and human validation.

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