NY Decision on Hepatitis C Drug Coverage May Spur More Pushback on Tight Policies

A dispute between the New York attorney general and various health insurers over their restrictive coverage of hepatitis C drugs could produce ripples that reach beyond that state. The situation is not the first such instance of pushback against payers’ coverage policies, and it’s certainly not the first example of resistance to policies specific to hepatitis C therapies. But it could very well serve as a catalyst for other groups that are fighting back on ever-tightening specialty drug coverage policies.

On April 26, New York Attorney General Eric Schneiderman (D) said that his office had made an agreement with seven health plans — Affinity Health Plan, Empire BlueCross BlueShield, Excellus Health Plan, HealthNow, Independent Health, United Healthcare/Oxford and MVP Health Plan — that will expand coverage for hepatitis C drugs to members who previously did not qualify. Less than two weeks before the settlement was announced, on April 14, the attorney general filed a lawsuit (Index No. 450471/2016) against another insurer, Capital District Physicians’ Health Plan, Inc. (CDPHP), for imposing restrictions on coverage for the medications that violate “the law and the insurer’s own policies.”

Various media reports have said Schneiderman asked 16 insurers for information on their coverage of the drugs. The attorney general’s office did not respond to an SPN request for information, including whether it plans to file additional lawsuits.

The deal calls for the insurers to “revise their coverage policies for chronic Hepatitis C treatment” for their commercial insurance plans, said the attorney general’s office.

Cigna Is Expanding Mandatory Genetic Counseling Program With Eye on Value

As genetic tests continue to flood the market, Cigna Corp. is preparing to expand its mandatory genetic counseling program with an eye on bringing value to an area that offers widely diverse value propositions.

As of July 15, the insurer will require that members undergo genetic counseling with an independent board-certified genetics specialist before taking a genetic test for:

- Whole exome sequencing;
- Hereditary cancers in addition to breast, ovarian and colorectal, which already required counseling as part of the initial pilot;
- Hereditary heart disease in addition to long QT syndrome, a heart rhythm disorder that can cause death and also was one of the conditions in the first phase of the program; and
- “Pediatric microarray analysis for children with certain developmental delays or intellectual disabilities.”

The insurer launched the initial pilot in September 2013 (SPN 8/13, p. 1), at which time it was the first national insurer to require genetic counseling before coverage.

Access a free copy of a recent issue of AIS’s Health Plan Week at http://files.aishealth.com/nlpdf/hpw.pdf
approval for genetic tests. Since that time, more than 32,000 Cigna members have undergone genetic counseling, with the plan seeing more than double its average number of monthly claims for the service.

In deciding what tests to include in the program’s expansion, “We continue to focus on genetic tests that are complex and are often misused or misinterpreted,” says Jeffrey Hankoff, M.D., Cigna’s medical officer for clinical performance and quality. “We looked carefully at incoming requests for genetic testing and chose the ones where we thought mandatory genetic counseling would provide the most value.”

During a Sept. 30 AIS webinar, Melissa Bennett, clinical policy director for the eviCore healthcare laboratory management program, noted the following about the current personalized medicine market:

- More than 5,000 genetic and molecular tests are available.
- Two to three tests are launched every week, almost two-thirds of which are related to oncology.
- Spending on these diagnostics “is increasing at an unsustainable 15% trend year over year.”
- The overall market, including companion diagnostics and targeted therapies, is worth $42 billion.

By 2016, the personalized medicine market is estimated to be worth more than $60 billion.

The market is driven mainly by products focused on oncology, cardiology and infectious disease.

Hankoff explains to SPN that the program’s goal “is to ensure that the right people are getting the right genetic test at the right time. We want to help people who are undergoing genetic testing obtain the information they need to make informed health care decisions. In many cases, these are decisions that can have life-altering implications.”

If patient-satisfaction surveys by InformedDNA, the company that provides genetic counseling for Cigna, are any indication, the program is fulfilling this goal. According to an InformedDNA survey of Cigna members who used the provider’s genetic counseling services in 2015, 95% of respondents “say they feel more informed about their genetic risks while 94 percent say they can make informed decisions about their hereditary risks.”

**Tests Must Have Clinical Value, Be Appropriate**

Hankoff declines to disclose what Cigna pays for genetic counseling: “Like other health care professionals, genetic counselors submit claims for the services that they provide. Contractual arrangements with genetic counselors are confidential as they would be for any other health care professional.”

However, “the costs vary widely” for the tests themselves, he says. “For those tests where we require genetic counseling, the cost starts at around about $2,500 and goes up from there. The genetic counseling program isn’t about cost; it’s about quality. We want to ensure that when an individual has a genetic test, it’s a test that has clinical value and is appropriate based on the individual’s health status and risk factors.”

Since the program’s inception, “We’ve seen an exponential increase in the number of genetic tests on the market, many of which have no proven clinical value. At the same time, there’s been a big push to convince consumers that they should get more and more tests. The result is that people are demanding more genetic testing that won’t be useful to them and can, in fact, cause harm. For example, they may get a false positive result, which can lead to more testing or even invasive medical procedures that are unnecessary and have their own risk factors. They may also get results that show they have a hereditary condition for which there’s no known medical intervention — and that information could become a part of their medical record that will follow them for the rest of their life.”

Contact Hankoff through Mark Slitt at mark.slitt@cigna.com.
Diplomat Looks to Boost Oncology Presence With Planned Deal for TNH

Diplomat Pharmacy, Inc. unveiled plans to make yet another specialty pharmacy acquisition, this time with an eye on expanding its oncology services. The company said April 28 that it had signed a definitive agreement to purchase Valley Campus Pharmacy, Inc., doing business as TNH Advanced Specialty Pharmacy, for $75 million. Diplomat said it expects the deal to close within 60 days.

According to Diplomat, TNH had 2015 revenues of about $400 million, up from $240 million in 2014 and $100 million the previous year. The company, which started in 2009 and is based in Van Nuys, Calif., is “one of the largest independent oncology-focused specialty pharmacies” and is “one of very few assets of this scale remaining in the market,” said Diplomat. About 53% of its business mix is in oncology, with hepatitis C and immunology making up most of the remaining mix. TNH has deals for 22 limited-distribution drugs, mainly in oncology, and has “relationships with over 1,700 referring prescribers,” as well as a “diverse payer mix,” said the purchaser. It does business in 34 states and territories.

TNH Will Help in California, Texas Markets

In addition, it “offers both revenue and cost synergies,” as well as “promising proprietary technology” known as TNH Live. The buyer notes that “some components of TNH’s portal can be leveraged across Diplomat’s platform.” And finally, it “strengthens Diplomat’s footprint in key geographic markets” — California and Texas.

Diplomat CEO and Chairman Phil Hagerman, R.Ph., said in a press release that his company “recently added a licensed Texas facility to enable brick and mortar presence for the State of Texas Medicaid program. According to a 2014 report by the American Association of Medicaid Pharmacy Administrators, Texas Medicaid serves 3.7 million patients. Our combined resources will make us stronger and more unique within the specialty services industry.”

The deal is one of multiple transactions that the more-than-40-year-old company — which went public in July 2014 (SPN 7/14, p. 1) — has made in fewer than three years. In June 2015, Diplomat purchased Brookhaven, Pa.-based Burman’s Specialty Pharmacy for $82.8 million, shoring up its hepatitis C capabilities (SPN 7/15, p. 1). In April 2015, Diplomat completed the purchase of BioRx, LLC for $315 million (SPN 3/15, p. 1). Cincinnati-based BioRx offers services for bleeding disorders, immunoglobulin therapy, hereditary angioedema, alpha-1 antitrypsin deficiency and nutrition/digestive disorders, according to its website. Prior to that, in June 2014, Diplomat acquired MedPro Rx, Inc. for $52 million (SPN 7/14, p. 8). Headquartered in Raleigh, N.C., MedPro is focused on immunodeficiencies, autoimmune neuromuscular disorders, hematologic disorders and certain rheumatologic conditions treated with intravenous immune globulin, subcutaneous immune globulin and clotting factor. And in December 2013, Diplomat bought American Homecare Federation, Inc. (AHF) for $13.4 million (SPN 2/14, p. 5). AHF, which is headquartered in Enfield, Conn., provides clotting factor and infusion supplies to patients nationwide and has a large presence in New England and the Northeast.

“The acquisition of TNH Specialty Pharmacy is not surprising,” Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC, maintains to SPN. “Companies that go public — or more commonly want to be acquired themselves — always seek out acquisitions not only to be more competitive but also to be accretive to their EBITDA [i.e., earnings before interest, tax, depreciation and amortization] line. I’ve seen this happen time and time again over many years. Wall Street analysts get excited when they see public companies acquire competitors and results materially impact their ‘buy/sell’ recommendations.”

However, continues Sullivan, “a side effect of going public is that it often changes the company culture from collegial entrepreneurship to one of having to satisfy Wall Street’s voracious hunger for strong financial performance on a daily basis. If you are benefitting from stock options, you are kicking your heels. If not, the culture change for associates is not always positive. Diplomat will need to work hard to preserve their independent spirit.”

Contact Sullivan at wsullivan@specialtyrxsolutions.com and Bob East at Westwicke Partners for Diplomat at (443) 213-0500.

Survey: Oncology Management Is Still an Important Payer Challenge

Managing oncology drugs and service, determining specialty drugs’ value and making sure treatments are clinically appropriate were the top reported challenges in 2015 from health plan respondents, according to the recently released EMD Serono Specialty Digest.

This year’s digest, the 12th edition, contains data from 58 commercial plans nationwide, representing more than 140 million covered lives. In June, EMD Serono will make available a new oncology-specific supplement to the digest.

Among the findings are the following:

◆ 41% of respondents said managing sites of care for infusions was their least successful challenge last year,
followed by 30% who said managing oncology. Conversely, 58% said that ensuring clinically appropriate use of drugs was their most successful challenge.

22% said that implementing new or enhanced utilization management or prior authorization was the “single most important initiative” their company undertook in 2015, followed by implementing a site-of-care initiative at 19% (see story, p. 6).

44% said they were using site-of-care programs, with 35% saying they would implement such a program within the next 12 months. Among those with programs in place, the main tactic was requiring a preferred site with some medical exceptions (68%), followed by contacting members to recommend alternate sites (44%), providing lower member cost sharing for preferred sites (32%) and requiring white bagging of drugs (20%).

Use of oncology pathways increased, with 38% of respondents using at least one pathway, up from 21% in 2014.

93% of respondents’ plans have a preferred agent among the new hepatitis C therapies, an increase from 53% the prior year (see box, p. 11).

23% of respondents used episode-of-care or bundled payments in 2015, up from 11% the previous year. However, 65% say they have no plans to implement such a reimbursement model.

14% have at least one outcomes-based contract for a specialty drug, with 30% planning to implement this within the next 12 months.

42% of respondents use partial-fill programs for specialty drugs, and 32% plan to implement this tactic within the next year. For oral oncology drugs — the most common therapeutic category to use this strategy, followed by oral hepatitis C drugs — the most common requirement is a partial fill for the first fill only (48%), followed by 19% requiring it for the first two fills.

Increased or enhanced prior authorization that’s based on a therapy’s clinical appropriateness and requiring members to be infused in less-costly sites of care were among the most likely design strategies that respondents said their companies would implement in the coming year (see chart, below).

Changing their PBM, reducing member out-of-pocket costs for biosimilars and implementing new or enhanced oncology clinical pathways were some of the least likely strategies to be implemented in the next year.

Download the digest at www.specialtydigest.emdserono.com. For more information, contact Melissa Manganello at (781) 681-2393.

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**Most Likely Design Strategies for the Coming Year**

Q: Which 3 benefit design strategies are you most likely to implement during the coming year?

Most likely design strategies include required use of lower-cost infusion sites and enhanced PA based on clinical appropriateness. Enhanced formulary review of new medications is also highly likely. Enhanced clinical PA predominates as the single most likely design strategy.

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Illinois Blues Plan and Oncology Group Form Intensive Medical Home

Two long-time partners recently launched a new oncology program to better manage patient care. Blue Cross and Blue Shield of Illinois (BCBSIL) and Illinois Cancer Specialists (ICS) are collaborating on what they say is the first oncology intensive medical home pilot program in that state.

ICS, which is in The US Oncology Network, “has been a partner of ours for a long time,” says Lee McGrath, senior director, provider network strategy for BCBSIL, and the group has provided “excellent quality of care for our members.”

For its part, “ICS chose to work with BCBS because the organizations were very aligned in improving community based oncology care,” says Brian Field, director of managed care for The US Oncology Network. “We approached them because they were already working on a medical home project in another specialty. We also pursued this with BCBS because of the influence in the Chicago market, as well as their place in our practice market share, [where] they are second behind only Medicare. We feel in an era to drive quality, outcomes and value that the specialist market, specifically oncology, can drive improvement. After sharing our program and resources available to us, BCBS felt we could make that difference as well.”

Crohn’s Pilot Has Promising Early Results

The Blues plan has other intensive medical homes, and its first specialty one was a pilot for Crohn’s disease with the Illinois Gastroenterology Group that was launched in late 2014 (SPN 11/14, p. 1). Early results have been promising: Cost of care declined by 10% over the first 10 months of the program, and there was a 57% reduction in hospitalization payments and a 53% drop in emergency room payments (SPN 4/16, p. 6).

McGrath clarifies that the “goal of a patient-centered medical home and an intensive medical home are the same: managing and coordinating the care of a patient.” But with a patient-centered medical home, “there is a governing body that says you have to do these 10 things, and now you’re a PCMH.”

BCBSIL members eligible for the oncology intensive medical home are those who are receiving chemotherapy or hormone therapy and have a diagnosis of breast, colon, lung, pancreatic or prostate cancer or non-Hodgkin’s lymphoma. Those conditions were selected because they “are the most prevalent at that practice,” explains McGrath. BCBSIL “looked at our claims” and is partnering with ICS “based on who they are seeing....We want to make sure we’re covering as many patients as we possibly can.”

The groups are hoping to enroll 150 to 200 patients per year. Enrollment is not automatic, though. According to Field, “We must first educate the patient about the program, and secure a signed consent and share that with BCBS.” Enrolled patients will be in the program for six months at a time and will be treated at one of the 10 ICS locations. If treatment needs to be provided for a longer period of time, McGrath says those members can continue in the program. “We want to support patients in any way possible.”

McGrath tells SPN that BCBSIL has been talking with other oncology practices about other pilots. In fact, in April the plan signed an agreement with one that she cannot disclose at this point.

At ICS, “our goals are quite simple,” Field tells SPN. “The program is designed to help meet the needs of patients, payers, and providers. We have sought to improve efficiency and quality by following evidence-based medicine, leading to the development of a patient-centered, value-based cancer care program.”

The providers are following the National Comprehensive Cancer Network’s NCCN Guidelines. “Our goal is to provide evidence-based validated, outcome-driven patient care,” says Field. “This type of quality care also has to meet the national quality standards that follow cost-effective pathways to provide access and affordability to patients — access to cancer care that is coordinated with the central focus on patients and their entire medical condition.”

McGrath says the Blues plan is looking for a “very, very, very high” percentage of compliance with the guidelines, but she notes that it will never be 100%. The practice of medicine “is an art, not [solely] science,” she tells SPN.

A “big differentiator” between care provided through the pilot and care that a member normally would receive is ICS’s use of a nurse care manager (NCM), says McGrath. This is an oncology certified nurse who can proactively manage patients.

According to Donna Krueger, clinical services administrator at ICS, “There is one care manager for all sites, and she is an employee of ICS.” The NCM, also known as a supportive care nurse (SCN), “is responsible

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for following up with all patients receiving chemotherapy (IV or oral) for the six major disease types chosen. She calls after each chemotherapy [treatment] at a minimum. Higher-risk patients or those having significant toxicity from treatment are called more frequently.”

Krueger tells SPN that “If the patient is having a problem that the SCN feels needs additional medical attention, she contacts the patient’s primary care site for further intervention. Examples include dehydration, fevers, inability to eat or protracted nausea or vomiting. These patients are brought into the office for intervention, which can often eliminate the need for an ED visit or an inpatient hospitalization. Education is also a high priority to help patients from getting into these situations — for example, discussing the need for good hand washing and staying away from sick people when their white blood cell counts are low, calling with fevers greater than 100.5 degrees, etc.”

BCBSIL and ICS plan to meet on a quarterly basis to “exchange information and discuss if the [intensive medical home] is a sustainable model for benefit and care delivery services,” says the Blues plan. “Some of the information discussed will include metrics on hospital admission rates, hospital days, ER visits, office visits and home health visits.”

Contact McGrath through Kristen Cunningham at kristen_cunningham@bcbsil.com and Field and Krueger through Christy Sullivan at christy.sullivan@usoncology.com.

Site-of-Care Program Saves Two Plans $1 Million Over Six Months

As payers struggle to contain the ever-growing costs of specialty therapies, one tactic that some are turning to is site-of-care management. And with more and more drugs being administered in the hospital outpatient department, which can apply quite the markup on therapies compared with other locations such as physicians’ offices or patients’ homes, this may be a challenging yet ultimately effective strategy to take.

Magellan Rx Management recently unveiled the early results of its clinical site-of-care program for two regional health plans — savings of more than $1 million over the first six months of the offering.

“Savings was calculated based on the difference in the member’s infusion drug cost when administered in the hospital outpatient facility versus the alternate site of service chosen (either physician office or home infusion provider) — both values are derived from the health plans’ medical benefit paid claims data,” explains Adam Wiatrowski, senior vice president and general manager, Magellan Rx Specialty. The drugs included in the calculation were those “used to treat autoimmune disorders, immunodeficiencies and rare diseases.”

According to the sixth edition of Magellan’s Medical Pharmacy Trend Report, “for both commercial and Medicare administration codes, the most spend occurs with administration of IV chemotherapy. Analysis of drug administration code spend is inclusive of all sites of service (home infusion/specialty pharmacy, hospital outpatient, and physician office) and as expected, administration of medical benefit drugs is more costly in the hospital outpatient facility than other outpatient sites of care. Frequently, it is four times more expensive in the hospital than physician office setting for commercial members; for Medicare, it is frequently twice as costly in the hospital.”

Based on health plan claims data, Magellan found, for example, that Remicade’s (infliximab) cost per claim was $4,132 in a physician’s office, $5,002 through home infusion or specialty pharmacy and $8,930 in the hospital outpatient department. And the cost per claim for Neulasta (pegfilgrastim) was $3,741 in the physician’s office, $3,731 through home infusion or specialty pharmacy and $7,207 in the hospital outpatient setting.

Nurses Reach Out to Patients

Through Magellan’s site-of-service program, which is run by a care team consisting of nurses, pharmacists and doctors, a referral center nurse will reach out to a patient receiving infusions to discuss all of the administration sites available, as well as benefits that each offers. “Payer and member savings are generated when the patient chooses a more cost-efficient location,” says Magellan. “Member affordability and convenience are the most common considerations for selecting an infusion provider.” In addition, people whose immune systems already are compromised are not putting themselves at risk for a hospital-acquired infection when they choose an alternate site.

Within the two health plans, there were “multiple transitions” of members from the hospital outpatient setting to physician offices and their own homes, Wiatrowski tells SPN. “The office-based practices with infusion suites and home infusion providers are both equally advantageous for members for different reasons.”

Wiatrowski says that he cannot reveal the plans’ identities or the regions in which they are located, but he does say that “the two health plans are located in different regions, proving the program works in different geographic areas, each containing their own unique networks and dynamics.”

For payers evaluating their medical pharmacy benefit management strategies, a site-of-service program is “a very important initiative, especially as we’re seeing...
hospitals buy physician practices and billing at the hospital rates, in addition to the growing pipeline which will further exacerbate this challenge,” he says. “It’s important for a health plan to have a medical pharmacy management strategy that consistently reviews and optimizes site of service.”


Contact Wiatrowski through Colleen Flanagan Johnson at CEFJohnson@magellanhealth.com.

**Multiple Drugs Are in Late-Stage Pipeline for Alzheimer’s Disease**

While innovation in many diseases has grown, one condition in which it hasn’t is Alzheimer’s disease, which is one of the leading causes of death. And with a huge older U.S. population, incidence of the disease is only expected to rise. But after a decade when Alzheimer’s drug development saw almost a 100% failure rate, there are now multiple drugs in late-stage clinical trials that could hit the market as early as 2018. In all, almost 20 drugs released the report, *Medicines in Development for Rare Diseases*, on May 10.

Orphan drugs are those used to treat rare diseases, which are conditions impacting fewer than 200,000 people in the United States. But as the report notes, “rare diseases, when taken together, are not that rare at all.” About 30 million people in the U.S. — approximately one out of every 10 individuals — have one of the 7,000 conditions classified as rare.

But small patient populations — sometimes only hundreds of people have a particular disease — mean more difficulty recruiting participants for clinical trials. In addition, research-and-development strategies may be complicated by the fact that these conditions often have complex underlying biological mechanisms. According to the report, FDA-approved treatments exist for only 5% of rare diseases.

However, in 2015, almost half — 47% — of new drugs approved were indicated to treat rare diseases, including eight first-in-class treatments and 11 new oncology drugs. According to the report, “Many of the new medicines provide treatment options for patients where there were few or none previously available.”

Over the last 10 years, the FDA has approved more than 230 new orphan drugs.

Researchers found that 566 medicines are in the orphan drug pipeline (see chart, left). Treatments for rare cancers and rare blood cancers lead the development pack, with 233 drugs. Therapies for genetic disorders such as cystic fibrosis are the second-largest group, with 148 medicines.

In addition, the report notes that some therapies offer new ways to attack diseases, including antisense therapeutics for amyotrophic lateral sclerosis and a fusion protein for beta thalassemia.

View the report at http://tinyurl.com/j5wcs8.

Contact PhRMA’s Jon Tripp at jtriipp@phrma.org.

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**PhRMA: Hundreds of Drugs Are in Development for Orphan Diseases**

Although the FDA continues to approve orphan drugs at an increasing rate, many rare diseases still have no treatments. But a new report shows that there is a robust pipeline of these therapies, which should hopefully help close the gap on having treatments available for many of these conditions.

The Pharmaceutical Research & Manufacturers of America, in collaboration with the ALS Association, released the report, *Medicines in Development for Rare Diseases*, on May 10.

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Contact PhRMA’s Jon Tripp at jtriipp@phrma.org.

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**Medicines in Development for Rare Diseases**

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NOTE: Some medicines may be in more than one category.
could finish testing and be available within five years. But some experts question whether the U.S. health care system is prepared to put these innovative new treatments into practice.

Alzheimer’s is the leading cause of dementia, which costs between $159 billion and $215 billion annually in the U.S., according to RAND Corp. That makes it more costly than cancer or heart disease, which are the leading causes of death. The Alzheimer’s Association points out that “Alzheimer’s is the only disease among the top 10 causes of death in America that cannot be prevented, cured or even slowed.”

Yet the condition receives much less funding, noted David Morgan, Ph.D., CEO of the Byrd Alzheimer’s Institute and a founding member of ResearchAgainstAlzheimer’s (RA2), during an April 11 webinar sponsored by nonprofit organization UsAgainstAlzheimer’s (UsA2). RA2 is a network of more than 400 Alzheimer’s researchers established by UsA2. Morgan attributed this to a “general ageist attitude with legislators” who “think of Alzheimer’s as an old-timers’ disease,” as well as the fact that there are “no survivors of the disease who can come forward” and say they were helped by a particular treatment.

According to a recent report sponsored by RA2, 17 drugs are in phase III trials. These treatments “are likely to finish testing and could be available to people with the disease in the next five years,” concludes the report, which is titled Will the Next Five Years Witness an Innovation Wave in Medicines for Alzheimer’s?

Also during the webinar, Drew Holzapfel, study lead and RA2 director, noted that just five treatments are available for people with the disease, and they only help delay or prevent symptoms from getting worse rather than treating the disease itself. “We’ve not seen a new novel drug since Namenda was launched in 2003....More innovation is obviously needed.” However, he said, even with an overall 10% success rate in drug development, “we should prepare for success rather than prepare for failure.”

2018 could see six new entrants to the Alzheimer’s treatment class, led by Eli Lilly and Co.’s solanezumab. Otsuka Pharmaceuticals, both alone and in collaboration with H. Lundbeck, has three of those possible entrants. Five medications are slated for a 2019 launch, four for 2020 and two for 2021. Solanezumab, said Holzapfel, would be the first of a “handful delivered via infusion.” And “close to 10 would be oral compounds.” In addition, notes the report, about 50 drugs are in phase II trials, with about 12 in phase II/III trials.

Morgan noted that some of the drugs undergoing trials likely “will have a symptomatic effect — they’ll treat the symptoms of the disease.” And while that may not be as good as a cure, he pointed out that drugs that increase dopamine levels in people with Parkinson’s disease treat symptoms of the condition, and “it’s extended life spans by 10 years for some people.”

Other treatments may help delay onset of the disease, and others may slow the rate at which it develops. With these, people “wouldn’t necessarily take the drug and feel better, but they will be better off one year from now.” The bottom line, contended Morgan, is that while a cure would be fantastic, what’s really needed are better, more effective treatments.

Is Health Care System Ready?

But even with all these drugs in late-stage trials, there are “barriers to accessing the drugs once they receive regulatory approval,” maintained Holzapfel. For one, “we need physicians to diagnose” people with Alzheimer’s. There is an “approximately 50% diagnosis rate,” which, “when you look at other conditions like cancer, is way lower,” he said. According to the report, 90% of people with cancer and cardiovascular disease have been given that diagnosis by their doctor.

Asked during the Q&A why the rate is so low, Holzapfel said that “physicians feel reluctant to deliver a diagnosis at times because of the treatments on the market.” With better drugs available, physicians “would be empowered to give a diagnosis” of Alzheimer’s, he contended.

In addition, said Morgan, primary care providers “don’t have the time it takes to do a meaningful cognitive analysis.” There now are 7,000 practicing geriatricians, but the report maintains that at least 30,000 will be needed by 2030 to treat the aging population, and the percentage of medical resident students entering the field is declining.

Reimbursement Can Be Problematic

Reimbursement can be an issue as well. “Medicare payer levels are very difficult to survive on,” maintained Morgan. “It’s difficult to run a clinic with 100% Medicare payer mix.”

And while an amyloid scanning tool is available, “it’s not reimbursed by Medicare, and it’s expensive,”
pointed out George Vradenburg, co-founder and chairman of UsA2.

That could change, though. The Imaging Dementia — Evidence for Amyloid Scanning (IDEAS) Study began patient enrollment last month, pointed out Holzapfel. According to the study’s website, it “will follow more than 18,000 Medicare beneficiaries to determine the clinical value of a brain” PET scan “to detect the hallmark brain amyloid accumulation of Alzheimer’s disease in diagnosing and managing treatment.” CMS will reimburse participating facilities and interpreting physicians for the scans under its Coverage with Evidence Development policy.

One listener asked if the speakers recommended testing for the apolipoprotein E-e4 (APOE-e4) gene, which is estimated to be a risk factor in up to one-quarter of Alzheimer’s cases. “It’s a mixed response,” said Morgan, who also is a professor at the college of medicine and molecular pharmacology and physiology at the University of South Florida. If an effective medication were available, he said he would “absolutely recommend” this test to determine a person’s risk. But in the absence of one, it’s up to whether individuals want to know their risk level or not.

View the report at http://tinyurl.com/h9nmbxb. For more information on the webinar, contact UsA2’s Tim Tassa at ttassa@usagainstalzheimers.org.

NEW FDA SPECIALTY APPROVALS

◆ April 13: The FDA cleared Abbott Laboratories’ Vysis CLL FISH Probe Kit as a companion diagnostic to Venetoxa (venetoclax). The AbbVie, Inc. and Genentech USA Inc. drug was approved April 11 to treat people with chronic lymphocytic leukemia with 17p deletion as determined by an FDA-approved test who have received at least one other therapy. Visit www.abbottmolecular.com.

◆ April 13: The FDA approved Epigenomics AG’s Epi proColon as the first and only FDA-approved blood-based colorectal cancer screening test. On May 9, Laboratory Corporation of America Holdings (LabCorp) became the first lab network in the U.S. to offer the test, which is being commercialized jointly by Polymedco, Inc. Visit www.epigenomics.com.

◆ April 16: The FDA granted an additional indication to Gilotrif (afatinib) for the second-line treatment of advanced squamous cell carcinoma of the lung. The Boehringer Ingelheim Pharmaceuticals, Inc. tablet also is indicated for the first-line treatment of specific types of EGFR mutation-positive non-small cell lung cancer. The Monthly Prescribing Reference website lists the price of 30 of the 40 mg tablets as $7,161. Visit www.gilotrif.com.

◆ April 25: The FDA gave an additional approval to Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) for use without ribavirin in patients with genotype 1b chronic hepatitis C virus infection and compensated cirrhosis. The AbbVie drug already has approval for use in other hepatitis C patient populations. The therapy costs more than $83,000. Visit www.viekirapak.com.

◆ April 25: The FDA approved Exelixis, Inc.’s Cabometyx (cabozantinib) for the treatment of advanced renal cell carcinoma in people who have received anti-angiogenic therapy. The agency gave the tablet breakthrough therapy designation, fast track status and priority review, with approval coming before its June 22 deadline. The wholesale acquisition cost for 30 days of 20 mg, 40 mg and 60 mg tablets is $13,750. Visit www.cabometryx.com.

Deal Could Prompt More Pushback

continued from p. 1

in a press release. “As a result of these agreements, nearly all commercial health insurance plans in New York State will cover treatment for chronic Hepatitis C without requiring members to develop advanced disease, such as liver scarring, and will not deny coverage because the member uses alcohol or drugs, or because the authorizing physician is not a specialist.”

When the FDA approved Gilead Sciences, Inc.’s Sovaldi (sofosbuvir) in late 2013 (SPN 12/13, p. 1), that medication was the first of a group of hepatitis C therapies that reduce most people’s viral loads enough that they are essentially cured of the disease. And whereas the previous regimens produced flu-like symptoms that often caused people to discontinue them, the newer drugs had far fewer side effects.

However, the new drugs’ prices — at least $1,000 per pill per day — offered serious challenges to payers’ efforts to contain ever-increasing specialty drug costs, prompting many to place stringent utilization management strategies on the drugs. And even with manufacturers Gilead — which also produces Harvoni (ledipasvir/sofosbuvir) — and AbbVie Inc. — which makes Viekira Pak (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) — offering rebates that cut the medica-
tions’ prices in half in some instances, many payers kept a tight lock on which members would be allowed access to the drugs. In January, Merck & Co. Inc. entered the field with Zepatier (elbasvir/grazoprevir), priced at almost half the cost of the other drugs (SPN 2/16, p. 1).

The management tactics include requiring a Metavir score of F3 or F4, indicating extensive fibrosis is present; requiring that a specialist prescribe the drug; and requiring the person to have advanced cirrhosis. A recent survey shows that payer respondents’ uses of such strategies for the most part increased from 2014 to 2015 (see box, p. 11).

But according to guidance from the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, treatment with the newest hepatitis C therapies “is recommended for all patients with chronic HCV [i.e., hepatitis C virus] infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.”

According to the attorney general’s press release, “By removing these three restrictive criteria, the insurers’ Hepatitis C coverage policies will more closely reflect evidence-based guidelines for treatment of chronic Hepatitis C infection.”

The insurers have 45 days to “fully implement the revised criteria,” and they must “send notices to members who were denied coverage who may now be eligible for treatment.”

Office Took Different Approach With CDPHP

In the complaint against CDPHP, the attorney general says that the health plan has said “it will cover all medically necessary care” to treat a disease. However, the suit contends, CDPHP is denying coverage “unless members demonstrate advanced disease — such as liver scarring or serious complications — even though medical consensus recommends treatment for nearly all individuals with Hepatitis C infection. By refusing to cover Hepatitis C treatment for members who have not yet developed advanced liver disease, based on undisclosed considerations of the cost of treatment, CDPHP is failing to satisfy its obligation to cover members’ medically necessary care and is deceiving its members about the scope of their coverage.”

In addition, says the lawsuit, “as internal documents reveal, CDPHP revised its Hepatitis C medical necessity criteria specifically to restrict coverage based on cost considerations. CDPHP’s medical necessity definition, however, fails to disclose to members and potential members that the cost of treatment will be a factor that CDPHP considers when evaluating if and when treatment is deemed medically necessary.”

In 2014 and 2015, “CDPHP denied almost half of its members’ claims for treatment.”

In a press release unveiling the lawsuit, Schneiderman said that “When consumers purchase health insurance, they rightfully expect that if they are diagnosed with a serious, potentially life threatening disease like Hepatitis C, treatment will be considered ‘medically necessary’ and covered by their insurance. Forcing patients to wait for care, risking internal organ damage, is unconscionable and, as we allege in our lawsuit, violates the law and the company’s own policies.”

CDPHP did not respond to an SPN request for more information.

Plan Says It Was Willing to Negotiate

However, an article in the Albany Business Review says that “CDPHP was willing to work on its policy with the attorney general and other regulators prior to being sued by the state,” according to Bob Hinckley, senior vice president for strategy and communications and chief strategy officer for CDPHP. The article says Hinckley said the insurer “told Schneiderman the issue of Hepatitis C drug coverage and his office’s concerns would be discussed at an April 13 pharmacy committee meeting,” but the following day the attorney general “chose to commence legal action instead. Simultaneously, the AG opened discussions with other health plans to negotiate their proposed policy changes. CDPHP expressed a willingness to join that agreement; however, the AG refused to allow our participation.”

According to Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC, “It is not in the least surprising that legal action is being initiated against a payer for restrictive prior-authorization policies that have been implemented for patients to ‘qualify’ for hepatitis C therapy based on the plan’s own medical criteria. These policies are akin to saying that you can’t get an antibiotic until your infection reaches a severe stage, and then we’ll review your case to see if you can ‘qualify’ for a prescription. In recent years, patient advocacy groups, such as the HIV and CF [i.e., cystic fibrosis] communities, have been successful in winning lawsuits against restrictive payer policies that put up barriers to access therapy at both the state and federal levels” (SPN 4/15, p. 1; 7/14, p. 1).

The deal that Schneiderman struck with the insurers “should result in improved access to expensive hepatitis C medications for patients within these seven health plans,” says Josh Golden, area senior vice president for Solid Benefit Guidance. “It obligates the plans to remove several prior-authorization criteria that may have prevented certain patients from obtaining coverage for these
products in the past. In that sense, it’s a win for patients, and a win for the manufacturers that have a product offering in this space — Gilead, AbbVie and Merck. But access comes at a cost, and widening coverage for these very expensive products may have downstream financial impact for these plans and their members.”

The impact of the agreement could be felt beyond New York, he says. “The outcome of this situation may end up moving the needle a bit in terms of how these drugs are covered by other plans at a national level. The scope of impact will depend on whether other state attorneys general follow suit with similar legal action.”

Sullivan notes that “Unless it is a federal suit it is not a universal precedent, per se. However, payers that sell nationally using the same medical criteria will be hard pressed to defend them with a precedent in another state.” He tells SPN that while it’s difficult to calculate how many people have been denied treatment with one of the drugs, “based on discussions with several of my specialty pharmacy clients, the estimated percentage varies greatly based on payer/PBM (especially with self-insured accounts not subject to ERISA), but the numbers are [that] approximately 40%” of prescriptions submitted for the hepatitis C drugs get approved.

Golden tells SPN that “Interestingly, the agreement focused on prior-authorization criteria, but did not address the question of formulary exclusion for these products. So even in the face of these legal challenges, we are still likely to see some plans continue to exclude specific products in this drug class, in an attempt to maximize rebate revenue.”

Ultimately, says Golden, “This situation is a reflection of the broader national debate around the rising cost of pharmaceuticals. Health plans and payers find themselves in a precarious position, balancing the demand for comprehensive medication coverage against the rising tide of specialty drug costs. The outcome of this particular situation suggests that, at least in the state of New York, the government is prepared to step in to defend the interests of the patient when it comes to drug coverage. But it does not address the underlying financial challenge that these plans face — and expanding coverage without regard to price may end up steepening the cost curve for plans and members over the long term.”

Nevertheless, Sullivan says to “start the tsunami watch. I believe the tide is rapidly pushing to the shore, bringing more lawsuits as patient groups band together spurred on by success in the courtroom. It is also a politically safe topic...especially when we are talking about diseases that are potentially fatal. Also remember that health plans hate to see their names in news articles, especially when they are being accused of letting people die.”

View the complaint at http://tinyurl.com/zphfmtv. Contact Golden at josh_golden@aig.com and Sullivan at wsullivan@specialtyrxsolutions.com.

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**Survey: Most Plans Increased Use of Hepatitis C Management Tactics**

When the newest class of hepatitis C therapies hit the market, they were greeted with mixed emotions. Physicians and patients — most of whom had been warehoused as they awaited treatment with the medications — welcomed the highly effective therapies that essentially offered a cure where one had not existed previously. Plus, patients were more likely to finish a regimen because the drugs didn’t come with the debilitating flu-like symptoms of earlier treatments.

But payers balked at the $1,000 per-day-plus costs of the therapies. In order to ensure proper use of the drugs, many instituted a variety of management strategies. The recently released 12th edition of the *EMD Serono Specialty Digest* (see story, p. 3) shows an increase from 2014 to 2015 in the use of most of these tactics.

In 2015, two-thirds of respondents required patients to have a specific fibrosis score for coverage approval of one of the drugs. Of those, 71% required a score of 3 or more.

Other findings include the following:

- **93% of responding payers had a preferred agent in 2015, up from 53% in 2014.**
- **57% of payers excluded coverage of nonpreferred agents, compared with 29% the previous year.**
- **77% based their coverage on a drug’s FDA label, up from 69%.**
- **66% limited treatment to responders, compared with 60%.**

Payers that tracked viral load responses remained the same in 2014 and 2015, at 70%. The only strategy that declined in use among respondents was requiring a behavioral contract, which 31% said they had in 2014, but only 25% reported in 2015.

BioScrip, Inc. reported a first-quarter 2016 net loss of $11.9 million, or 17 cents per share, compared with a net loss of $18.9 million, or 28 cents per share, for first-quarter 2015. The infusion services provider had revenue of $238.5 million in the most recent quarter, compared with $244.4 million for the year-ago period. The company attributed the decrease to its “planned shift in revenue mix to greater core revenues away from lower margin chronic conditions.” Visit www.bioscrip.com.

Diplomat Pharmacy, Inc. reported first-quarter 2016 net income of $15.4 million, or 24 cents per share, compared with $2.9 million, or 6 cents per share, for the year-ago period. The specialty pharmacy said it had $996 million in revenue for the most recent quarter, up 59% from $625 million in first-quarter 2015. It attributed the increase primarily to organic growth, “including approximately $122 million from increased volume and a richer mix of those drugs that existed a year ago, approximately $62 million from the impact of manufacturer price increases, and approximately $42 million of revenue from drugs that were new in the past year. The remaining increase was the result of approximately $145 million from our acquisitions.” Visit http://diplomat.is.

Blue Cross Blue Shield of Michigan extended coverage to Optune for its members with newly diagnosed or recurrent glioblastoma. The Novocure Inc. device delivers low-intensity, alternating electric fields through electrodes placed on the scalp. Contact Novocure’s Ashley Cordova at acordova@novocure.com.

Savings for home infusion compared with other administration sites ranged from $1,928 to $2,974 per course of treatment, according to a study by the CVS Health Research Institute. Researchers studied peer-reviewed research for multiple conditions, including cystic fibrosis, several cancers that require infused chemotherapy treatments and antibiotic treatment after orthopedic surgery. Patient outcomes were “as good or better” for people infused at home compared with those receiving the same therapy in a hospital or clinic. “In addition, patients overwhelmingly preferred receiving their infusion therapies at home, reporting fewer disruptions in personal schedules and responsibilities,” says the study, which was published April 29 in Healthcare: The Journal of Delivery Science and Innovation. View it at http://tinyurl.com/zt5kn22.

PEOPLE ON THE MOVE: Diplomat promoted Jennifer Hagerman, Pharm.D., to vice president of education and quality. ZappRx, a specialty drug prescribing platform, named Lorrie Carr chief commercial officer. She previously was divisional vice president, enterprise specialty sales and product management for Walgreen Co.

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