

SPECIALTY PHARMACY NEWS

News and Strategies for Managing High-Cost Biotech, Infusible and Injectable Products

Contents

- 3** The Apothecary Shops Launches Hepatitis B And C Pilot Program
- 3** Selected Specialty WACs Keep Rising, but at Slightly Lower Pace
- 4** Aetna Inks Deal With US Oncology, Will Launch Program in Texas
- 5** Plans Use Clinical Protocols to Manage Specialty Therapies
- 5** *Table:* Plan Use of Selected Management Tools for Biologic Agents
- 6** Genzyme Unveils Consent Decree Terms, Will Pay \$175M Up Front
- 6** *New FDA Specialty Drug Approvals*
- 7** Familiar Classes Are at Top of Medco Specialty Trend Drivers
- 8** Part B Report Shows Minor Impact From ASP, Other Reforms
- 11** Will Provenge Price Tag Prompt Closer Look at Benefit Designs?
- 12** *News Briefs*

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Long-Awaited Prostate Cancer Therapy Approved, but Use May Be Limited Initially

Three years after the FDA requested more clinical trials data for its Biologics License Application, the prostate cancer therapeutic vaccine Provenge (sipuleucel-T) has finally been approved. And while most industry expectations seem to be that health plans will cover the drug, many are doing so with a set of prior-authorization requirements to make sure it is used appropriately. But a series of factors may, in fact, limit uptake of the therapy, at least initially.

One of those factors may be Provenge's cost. While analysts estimated the drug would come to market with a price tag of about \$60,000 for a treatment regimen, manufacturer Dendreon Corp. raised a few eyebrows when it unveiled a cost of \$93,000. A regimen of Provenge consists of three infusions over a one-month period, at \$31,000 per infusion.

Dendreon did not respond to *SPN* requests for comment. The company has said it will donate money to a nonprofit organization that can help patients with copayments.

"The cost is not unprecedented," says Matthew Riordan, manager at Putnam Associates, a pharmaceutical and biotechnology consulting firm. "Avastin can cost \$100,000 per year for a whole course, and Erbitux is not far behind. Hemophilia with inhibitors can be at \$1 million or more for a year."

An autologous cellular immunotherapy, Provenge is the first of its kind to receive FDA approval. "The concept is old, but the mechanism is new," notes Al Heaton, Pharm.D., director of pharmacy management at UCare.

continued on p. 9

FDA, Congressional Interest in DTC Genetic Tests May Signal Greater Focus on Safety

In a situation that seems to be changing daily, companies who sell direct-to-consumer (DTC) genetic tests are coming under increased scrutiny from the FDA and Congress sparked by the unveiling of a pair of deals that would have made one particular product available in a couple of retail pharmacies. The ensuing developments seem to indicate a growing concern around helping ensure consumer safety, which may be particularly amplified in the current political environment.

Pathway Genomics Corp. recently unveiled a deal that would allow consumers to purchase its Insight Saliva Collection Kit off the shelves at Walgreen Co. and CVS Caremark Corp. retail stores. The kit can indicate whether a person carries genes for diseases such as cystic fibrosis and Alzheimer's and what their responses to some drugs would be.

But following that announcement, the FDA quickly fired off a letter to Pathway in which it contended that the kit "appears to meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act." Because of

that contention, argued the FDA, the agency needs to approve the kit before it can be sold.

Walgreens soon said that it would hold off on plans to sell the product, a statement echoed by CVS Caremark. But by then the situation had caught the eye of the House Committee on Energy and Commerce, which sent a letter requesting information to Pathway and a pair of companies that also sell DTC genetic tests.

But since DTC genetic tests are easily purchased online, why all the hubbub now?

“Going retail in a big way finally put the big spotlight on the issue of genetic testing,” contends Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC.

In addition to “greater visibility and greater access,” says Elan Rubinstein, Pharm.D., founder and principal of consulting firm EB Rubinstein Associates, “there are so many more such tests for so many more things with more potential for problems.” The idea that “bad results

could have bad consequences” is not new, he says, “but there is more risk of that happening now.”

New leadership at the FDA that has “more of a safety focus, including consumer protection,” also may have prompted the agency to step in, says F. Randy Vogenberg, Ph.D., co-founder of pharmaceutical consulting firm Employer-based Pharmaceutical Strategies, LLC. “This has been an area of underregulation...and given the overall change in market access to these products, the timing seemed right to put a ‘hold’ on them.” The FDA’s action, he tells *SPN*, also sends a general message that even though it is fairly easy for consumers to purchase these products, “these tests are not well-understood and could lead to problems in interpretation by consumers as well as health care professionals.”

Sullivan adds that “the FDA is very self-conscious of their image in the post-health care legislation environment. They are increasingly under a microscope to see how they will handle things like biosimilar biologics — and genetic testing does not fall far from that tree.”

On the surface the issue “doesn’t seem to be...highly political,” according to Rubinstein. But, as Vogenberg notes, “the safety and advocacy of consumers has taken a front position over the past year, and with elections looming, only more activity and attention will be placed by Congress on showing that they are working on behalf of their constituents.”

FDA Zeroes In on Interpretation

Dan Vorhaus, an attorney at Robinson, Bradshaw & Hinson and editor of the Genomics Law Report blog, tells *SPN* sister publication *Drug Benefit News* that the FDA’s response to the situation “strongly suggests that the FDA is focusing its regulatory attention on Pathway’s actual genetic test and its subsequent interpretation of the test results.” If that’s the case, he argues, “it’s difficult to see other DTC genetic testing companies escaping increased regulatory scrutiny.”

And more scrutiny may very well be needed, say experts.

“Despite attempts for public education, labeling and being careful about claims or use, there remains wide variation in success on all those fronts, coupled with growing concerns around privacy of all personal information,” Vogenberg says. He notes that the health reform law underscored this point by “further strengthen[ing] patient privacy and information control over health care information just as we are expanding electronic access to the same information.”

However, says Sullivan, regulations for “safeguards, who can /should be involved and what ongoing oversight needs to be provided” are still needed.

Specialty Pharmacy News (ISSN: 1937-6685) is published 12 times a year by Atlantic Information Services, Inc., 1100 17th Street, NW, Suite 300, Washington, D.C. 20036, 800-521-4323, www.AISHealth.com.

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The Apothecary Shops Launches Hepatitis B and C Pilot Program

One rapidly growing specialty pharmacy recently started a pilot program that it hopes will increase treatment success for people with hepatitis B and C. The Apothecary Shops is offering the program at its 17 specialty pharmacies in seven states.

Eric Sredzinski, Pharm.D., vice president of clinical affairs for The Apothecary Shops, tells *SPN* that the company runs and manages the program, which is free for patients, by itself. Asked about the cost of the program, he says the specialty pharmacy has "not looked at the direct costs involved. Our goal is to assist clinicians [to] manage their patients by leveraging the resources we have in place."

The company's pharmacists specialize in such areas as infectious disease, oncology, ophthalmology, fertility and transplants. According to Sredzinski, hepatitis B and

C fit "perfectly with the services our pharmacists are currently providing to educate a patient about their therapy, which can be challenging to manage."

In addition to coordinating with patients and physicians, The Apothecary Shops will offer counseling, depression screening and injection training. Patient consultations will include information on side effects, which can often hamper patient compliance (*SPN 12/08, p. 1*). Pharmacists also will contact patients' physicians about the information they gather during consultations.

In addition to eventually causing fibrosis and cirrhosis, chronic hepatitis also can result in liver cancer. From 2001 to 2006, the rate of one kind of liver cancer, hepatocellular carcinoma, increased 3.5% annually, according to a recent CDC report, which also cited chronic hepatitis B and C as "major risk factors" for the disease. The study also noted that hepatitis B and C are responsible for almost 80% of hepatocellular carcinoma around the world.

The study, which appeared in the May 7 *Morbidity and Mortality Weekly Report*, estimated that between 3.8 million and 5.3 million in the U.S. have chronic hepatitis — but "most are unaware of their infection."

Once people have received a diagnosis, ensuring they complete a course of treatment, which can take less than a year, is critical. When people with viral hepatitis are compliant with their treatment, there is a good chance they can achieve a sustained virological response. Sred-

Selected Specialty WACs Keep Rising, but at Slightly Lower Pace

While prices for brand-name drugs often used by Medicare beneficiaries continued to rise overall, the increase in costs for specialty therapies eased somewhat over the past year, says a report released in May. According to AARP's Public Policy Institute's *Rx Watchdog Report*, from April 2009 to March 2010 manufacturer prices for brand drugs increased 9.7%, compared with a 0.3% increase in general inflation. For that same period of time, prices for 144 specialty drugs used widely by Medicare beneficiaries rose 9.2%, which was down slightly from the 9.6% increase for 2009.

The report acknowledges that the wholesale acquisition costs (WACs) on which the authors have based their analysis may be higher than what purchasers paid due to discounts and rebates.

About two-thirds of the specialty drugs surveyed increased in price. Four of the five drugs that experienced the biggest WAC increases were multiple sclerosis therapies:

- ◆ *Betaseron (interferon beta-1b) 0.3 mg injection* — 25.7%
- ◆ *Copaxone (glatiramer acetate) 20 mg/ml kit* — 24.8%
- ◆ *Avonex (interferon beta-1a) 60 mcg/ml kit* — 19.9%
- ◆ *Rebif (interferon beta-1a) 88 ml injection* — 15.2%

The other therapy in the top five was oncolytic Gleevec (imatinib mesylate), 400 mg tablets, which experienced a 15.6% price increase.

The report also noted that the average cost for a specialty therapy over the same stretch of time was \$34,550. The average change in the cost of therapy was an increase of \$2,760, compared with \$3,194 for 2009 and \$3,254 for 2008, the year that experienced the highest jump since the Medicare Part D program began in 2006.

View the report at www.aarp.org/health/drugs-supplements/rx_watchdog.

zinski says that outcome “is the single most important goal of this effort.”

He explains that there are two sets of outcomes that the company will study in order to determine whether it will expand the initiative: clinician and patient interest in the model and patient adherence to treatment regimens. “We expect these and other outcomes will demonstrate the need for us to continue the initiative and to apply those practices with new medications available in the next 12 months,” he says.

The company also is offering one-time consultations to people with hepatitis B or C regardless of whether they get their medications at an Apothecary Shops pharmacy or another pharmacy.

Contact Sredzinski through Steve Carr at (602) 317-3040. View the CDC report at cdc.gov/mmwr. ✧

Aetna Inks Deal With US Oncology, Will Launch Program in Texas

After the success of a recent study, Aetna Inc. has tapped US Oncology Inc. to provide comprehensive cancer care for its members and participating oncologists.

US Oncology subsidiary Innovent Oncology will apply US Oncology’s Level I Pathways, evidence-based guidelines developed and managed by physicians within the US Oncology network. It will also provide proactive patient support services and advance care planning.

Aetna is the first national plan to offer the program, which launches June 1 in Texas and will serve the insurer’s fully insured commercial medical plans. According to Roy Beveridge, M.D., medical director for US Oncology, “Aetna asked to begin the program in Texas due to the large enrollment they have in the state.”

The state was also a very appropriate starting point for the Texas-based US Oncology. For one, Texas Oncology is the biggest community-based practice within the US Oncology network and has more than 300 physicians; it also “offers the largest number of physicians who have been implementing the program informally (without a payer counterpart),” says Jennifer Horspool, spokesperson for US Oncology.

Also, she says, the Texas practices have fully implemented US Oncology’s cancer-specific electronic health record, known as iKnowMed, “which provides Aetna and Innovent Oncology a better opportunity to measure the impact of the program on patients and overall cost.”

The offering should expand to other states next year, say the companies.

The program will focus on the following 14 cancers, which were chosen because they are the most commonly diagnosed, explains Horspool:

- (1) *Breast cancer,*
- (2) *and (3) Colorectal cancer* (two Pathways, one for colon and one for rectal),
- (4) *Prostate cancer,*
- (5), (6) *and (7) Indolent non Hodgkin lymphoma* (three Pathways for three disease types),
- (8) *Hodgkin’s lymphoma,*
- (9) *Non-small cell lung cancer (NSCLC),*
- (10) *Small cell lung cancer,*
- (11) *Ovarian cancer,*
- (12) *Multiple myeloma,*
- (13) *Pancreatic cancer* and
- (14) *Chronic lymphocytic leukemia.*

“These cancers are managed most often in the outpatient community-based setting, and chemotherapy is a key treatment modality — suggesting the need for an evidence-based medicine pathway,” explains Beveridge.

Results of a study that were released in January showed that adhering to evidence-based care in the treatment of NSCLC produced an average 12-month savings of 35%. In addition, there was no difference in patient outcomes between those treated with an evidence-based guidelines approach and those treated with a nonevidence-based approach.

“We were quite successful in the study with NSCLC,” Horspool tells *SPN*. “Those are not necessarily the expected results for all 14 of the cancers, but we do expect to see success with all 14 cancers.”

Beveridge tells *SPN* that “savings vary greatly based upon the number of patients and the stage and type of cancer. Overall, we believe that similar savings are a realistic expectation, but are more concerned that patients have access to evidence-based care to provide the best opportunity for survival.”

In other US Oncology news, the company also recently launched its Payer Quality Services offering for physicians who join the United Network of US Oncology through its Targeted Physician Services relationship.

“Payer Quality Services offers access to clinical quality benchmarking, patient and referring physician satisfaction surveys and managed care contracting services,” explains Beveridge. “Some of the Innovent Oncology product components are available to physicians who purchase services through Payer Quality Services, including Level I Pathways.”

The offering will bring oncologists and payers together through pay-for-performance initiatives based on evidence-based care that will help align reimbursement, says US Oncology.

Contact Horspool at (281) 863-6739. ✧

Plans Use Clinical Protocols To Manage Specialty Therapies

As specialty drug costs continue to climb, health plans increasingly are turning to more clinical management tactics to make sure the use of these therapies is appropriate, according to survey responses included in the 2010 *Biotechnology Monitor & Survey*.

Emron surveyed multiple health plans (including commercial/group, Medicare Advantage and managed Medicaid), PBMs, specialty pharmacy providers, employers, rheumatologists and oncologists for the third edition of the study.

Most health plans estimated that they were experiencing 11% to 15% annual growth in the use of biologics. What this means, says Steve Avey, vice president of managed care at Partners Rx Management, LLC, is that 3% to 5% of paid pharmacy claims are for specialty drugs. "This has come up substantially in just the last year," he tells *SPN*. "Every time you raise use by 1%, it has a 3% to 4% impact on the cost side."

Focus Grows on Evidence-Based Prescribing

"There will be a tremendous emphasis on evidence-based prescribing," says Avey. And oncology — which plans have been very hands off with — will be "no longer treated as a sacred cow."

Plans increasingly are putting prior authorizations on specialty drugs to make sure the prescribed use is for an FDA-approved indication, he says. And if there's not, then they're making sure the use is at least within industry-accepted guidelines (see table, right).

"More plans are looking to national guidelines," such as those by organizations like the National Comprehensive Cancer Network, maintains Avey. "Over the last three to five years, oncology prescribing has been more often by protocol. It used to be by look and feel."

Oncologist respondents "interestingly enough...are OK with that," he says. "It's taking the onus off of them. In a lot of cases, families want oncologists to do a lot of things that they may not feel are in the best interest of the patient or won't help the patient," but oncologists will do those things because the patient or the patient's family pressures them to. "Oncologists would just as soon put the onus on a health plan or PBM...and say, 'There's nothing I can do — the drug is not recognized for this indication, and there's no peer-reviewed article.'"

Employer respondents "are really focused on individual case management" of employees on specialty therapies, Avey says. "They have case management companies they usually contract with, and they really utilize those companies to help manage people taking biologicals."

The growth of specialty pharmacy providers the last two years "is unbelievable; they're growing by leaps and bounds," he says. These companies are not just distributors any more either. "Before, they were all about better pricing, doing a better job delivering drugs to members. Now, they are really moving beyond that."

And these specialty providers are doing their own form of case management, although they tend to call it "care management," he says. "Most specialty pharmacy providers have 14 or 15 disease states they do care management for." And their focus is not just on adherence but also on side effect monitoring and calling patients to engage them about issues surrounding their disease and treatment regimen.

One surprising trend among specialty providers is that "most are coming out with patient-assistance programs," Avey notes. "They're not just from manufacturers." And when a Medicare member hits the doughnut hole coverage gap, "specialty pharmacy providers are

Commercial/Group Plan Use of Selected Management Tools for Biologic Agents			
	Using in 2009	Will Institute in 2010	Total
Limit coverage for any biologic agent to its FDA-approved indication(s)	64.1%	12.8%	76.9%
Shift injectable agent(s) to specialty pharmacy provider management	39.7%	11.5%	51.2%
Require evidence of therapeutic efficacy through reports of specific patient outcome(s) to continue coverage of an approved biologic treatment	34.6%	17.9%	52.5%
Shift injectable/infused agent(s) from medical to pharmacy benefit management	32.1%	21.8%	53.9%
Institute information technology upgrades that help you better monitor use of biologic therapies on the medical benefit side of the business	23.1%	35.9%	59.0%
Institute a new individualized case management program for a condition treated with biologics	20.5%	23.1%	43.6%
Provide a new treatment algorithm/protocol to plan providers for a condition treated with biologics	14.1%	29.5%	43.6%
Provide comparative prescribing practice data regarding any biologic therapies to your network providers	14.1%	28.2%	42.3%
Provide cost-of-regimen information to providers related to a biologic intervention	10.3%	24.4%	34.7%

NOTE: Applied to at least one or more biologics.
 SOURCE/METHODOLOGY: Emron, *Biotechnology Monitor & Survey*, 2010 edition. Sponsored by Bristol-Myers Squibb Co., released May 2010. The data reflect the responses of 78 commercial/group health plans representing 121,390,716 covered lives.

taking it upon themselves...to reach out" and let the member know about organizations that can offer payment assistance, he says.

Avey maintains that another unexpected finding was that "about 30% of health plans are doing their own internal outcomes analysis, in which they monitor how much the drug costs and what patient outcomes are," and then compare these data with information on other drugs available for the condition.

Contact Avey at steve.avey@partnersrx.com. View the study at www.biotechmonitor.com. ✦

Genzyme Unveils Consent Decree Terms, Will Pay \$175M Up Front

Following contamination issues with one of its manufacturing plants that impacted the availability of a handful of specialty therapies, Genzyme Corp. has unveiled the final terms of the consent decree the FDA has imposed upon it to make sure the Allston, Mass., factory complies with good manufacturing practice regulations (*SPN 4/10, p. 5*).

The Allston plant manufactures Gaucher disease therapy Cerezyme (imiglucerase for injection) and Fabry disease drug Fabrazyme (agalsidase beta). Thyrogen (thyrotropin alfa for injection), which is indicated for people with thyroid cancer, is filled and finished at the facility. The company had previously filled and finished Pompe disease treatment Myozyme (alglucosidase alfa)

at the Allston facility, but it recently gained regulatory approval to shift that activity to its Waterford, Ireland, plant.

The company has had problems at the Allston plant since last summer. In June 2009, Genzyme said that it had detected a virus in a bioreactor at the plant that impacted production of Cerezyme and Fabrazyme, causing a subsequent shortage of the therapies (*SPN 9/09, p. 5*). The company initially said it expected the Cerezyme shortage to end last October. But on Aug. 10, 2009, Genzyme said it expected the shortage to last through the end of the year, with shipments resuming in November and December. The company also said it expected to resume product shipments of Fabrazyme at the same time.

However, in February 2010, the company said it was still undergoing supply issues with Cerezyme and Fabrazyme (*SPN 3/10, p. 12*). On Feb. 23, the company said it had delayed Cerezyme shipments in January and February and would reduce by 50% the amount of the drug supplied for the next eight weeks. Genzyme also said it would not achieve its goal of meeting 70% global demand for Fabrazyme by April, so it was extending the current supply allocation.

When it disclosed the final terms of the consent decree, Genzyme also noted that it is shipping Cerezyme at about 50% of demand and Fabrazyme at about 30%. According to the company, it will give a detailed evaluation of supply in June.

NEW FDA SPECIALTY DRUG APPROVALS

◆ **April 28: The FDA granted an additional approval to the Abbott drug Kaletra (lopinavir and ritonavir) as a once-daily treatment for adults with HIV who have taken antiretroviral therapy.** The drug was approved 10 years ago for adults who have not taken antiretroviral therapy. According to drugstore.com, 100 of the 25 mg tablets cost \$306.63, and 100 of the 50 mg tablets cost \$648.82. Visit www.kaletra.com.

◆ **April 29: The FDA approved Dendreon Corp.'s Provenge (sipuleucel-T) for the treatment of asymptomatic or minimally symptomatic, metastatic, hormone-refractory prostate cancer.** An autologous cellular immunotherapy, the drug is the first of its kind to receive FDA approval. A regimen of Provenge consists of three infusions over a one-month period, and each dose is made using an individual patient's cells that are processed with a recombinant protein that activates that patient's im-

mune system. Each infusion costs \$31,000, for a total regimen cost of \$93,000. Visit www.provenge.com.

◆ **May 25: The FDA approved Genzyme Corp.'s Lumizyme (alglucosidase alfa) for the treatment of late-onset Pompe disease.** The recommended dose of the infusible therapy is 20 mg/kg of body weight every two weeks. Genzyme received FDA approval in 2006 for the Pompe disease drug Myozyme (alglucosidase alfa). When the company transitioned the drug to a bioreactor with more capacity in order to scale up production, the FDA deemed the resulting product — Lumizyme — a new drug that required its own approval. A Genzyme spokesperson says that Lumizyme "will be priced similarly to other enzyme replacement therapies, including Myozyme." For an adult, Myozyme can run around \$300,000 per year, with a price tag around \$30,000 for a child. Visit www.lumizyme.com.

Among the consent decree terms are the following:

- ◆ **The company will pay the federal government \$175 million** “in unlawful profits from the sale of products that were made at the plant,” according to the FDA.
- ◆ **Genzyme will move fill/finish operations** for Cerzyme, Fabrazyme and Thyrogen sold within the U.S. from the Allston facility by Nov. 28, 2010. For these therapies sold outside the U.S., the company must shift the fill/finish operations by Aug. 31, 2011. If the firm does not meet these deadlines, the FDA may require it to pay the government 18.5% of revenue from these products.
- ◆ **Genzyme is working with third-party consultant** Quantic Group Ltd. on a comprehensive remediation plan, which it will submit to the FDA for approval. The

manufacturer says it expects that plan to be complete in two to three years. There are compliance milestones Genzyme must meet during this time, and failing to do so could result in its paying \$15,000 per day per affected drug until it has met those requirements. Quantic will oversee the company during this time.

- ◆ **After the plan has been completed**, Quantic will continue to oversee the company for five years and will submit annual reports to the FDA.

The consent decree was filed May 24 in the U.S. District Court for the District of Massachusetts and is subject to court approval.

Visit the Genzyme supply update website at supply-update.genzyme.com. ♦

Familiar Therapeutic Classes Are at Top of Medco Specialty Trend Drivers

Although specialty trend did not increase as much in 2009 as it did in 2008 for one PBM, costs are still rising at a double-digit rate. According to Medco Health Solutions, Inc.’s 2010 *Drug Trend Report*, the combination of utilization and unit cost boosted specialty trend 14.7% last year, down slightly from the 15.8% increase it experienced in 2008.

Medco notes, though, that there is a widening gap between utilization and unit cost. As drug prices continue to rise (see story, p. 3), the unit cost trend has grown from 8.8% in 2006 to 12.1% in 2009. During the same period utilization growth, however, has decreased from a 7.3% increase to only 2.6% last year.

The leading therapeutic classes contributing to specialty trend were multiple sclerosis (31.1%, up from 26.1% in 2008), which was boosted by a 22.7% increase in cost per day; rheumatoid arthritis and other autoimmune conditions (25.6%, down from 30.1% in 2008); and cancer (15.5%, down from 16.5% in 2008). With two new therapies gaining FDA approval in 2009, pulmonary arterial hypertension treatments experienced the biggest year-to-year change in trend, 33.2%.

Anemia, hepatitis, osteoporosis and specialty HIV therapies exerted a downward pull on the specialty trend, helping moderate it.

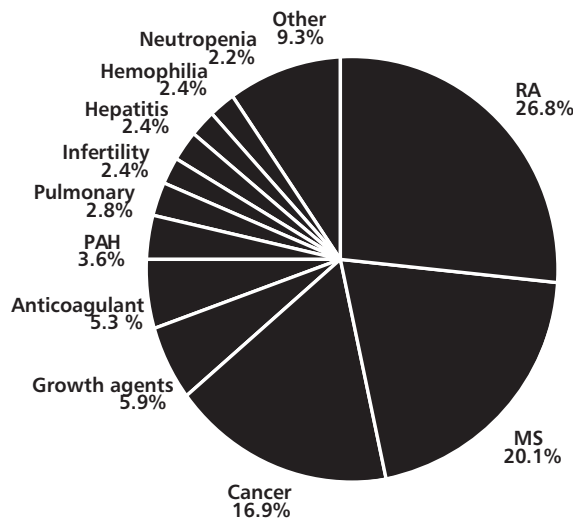
Specialty drug spend made up 14.2% of total per-employee per-month spend. The main contributing specialty therapeutic classes to cost were, again, rheumatoid arthritis and autoimmune disorders, multiple sclerosis and cancer (see chart, right).

According to Robert Epstein, M.D., Medco’s chief medical officer, the data in the report are from the PBM’s top 200 clients.

View the 2010 *Drug Trend Report* at www.drug-trend.com/art/drug_trend/pdf/DT_Report_2010.pdf.

RA and MS Contribute Most to Plan Costs for Specialty

Contribution to net plan specialty costs by category



RA = rheumatoid arthritis and includes other immune disorders; MS = multiple sclerosis; PAH = pulmonary arterial hypertension. Other = all categories contributing < 2.2% to net plan specialty costs: anemia, HIV, immune deficiency, metabolic disorders, ophthalmics, osteoarthritis, osteoporosis, respiratory syncytial virus. Percentages are rounded and may not add up to 100%.

SOURCE: Medco Health Solutions, Inc., *Drug Trend Report*, released May 2010.

Part B Report Shows Minor Impact, But Excludes Recent MD Changes

Many people within the pharmaceutical industry say the reimbursement changes mandated by the 2003 Medicare reform law have had wide-reaching effects across a variety of stakeholders and specialties. However, according to a recently released report, *Part B Drug Payment Reform: Lower Expenditures without Signs of Adverse Effects*, other than reductions in Medicare revenue for providers, changes in reimbursement had little impact on most of the areas studied. But one provider contends that had the study covered even one additional year, the findings may have been quite different.

The 2003 Medicare reform law put in place multiple methods to attempt to more accurately reflect market prices on Part B drugs and biologicals. In 2003, Medicare paid \$10.3 billion for Part B drugs. Although annual expenditures for these drugs have remained at more than \$10 billion since those changes, "their growth has slowed considerably," says the report.

Among the changes, the Part B payment methodology rate for most drugs shifted from 95% of average wholesale price to 85% of AWP as of Jan. 1, 2004. And then one year later, that methodology shifted to 106% of the average sales price (ASP). The law also temporarily increased payments to physicians for drug administration by 32% in 2004 and then 3% in 2005, at which time CMS also shifted to a new set of codes for drug administration. Additional changes for physicians accompanied these.

For the report, CMS contracted with Mathematica Policy Research, Inc. to study Medicare claims data for 2000 through 2007, although, as they note, "we cannot say how much (if any) of the observed changes between the baseline and follow-up periods are due specifically to the policy reforms of interest."

Physician Behavior Remained Similar

Among the findings with respect to physicians are the following:

- ◆ *Physicians appeared to not make any big changes to their treatment behavior*, including treating Medicare beneficiaries and changing the types of services they provided.
- ◆ *There was not a difference in willingness to treat Medicare beneficiaries* between physicians in solo providers and those in group practices.
- ◆ *"Abrupt blunting or cessation of previous sharp increases in payments"* to specialists in allergy-immunology, rheumatology and hematology-oncology occurred at the same time the new payment system was installed.

According to Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC, though, some providers have little choice in patient mix. "If you are a specialist that, by nature of the specialty, has a disproportionate mix of Medicare eligibles, you don't have much wiggle room to stop seeing these patients short of changing specialties," he tells *SPN*.

Solo practitioners, he adds, "are at a distinct disadvantage since they typically have limited business management skills and poor access to data to even know how well or badly they are doing financially." He points out that the study "does not quantify how many of these physicians have since joined larger practices."

Fewer Solo, Small-Group Practices Exist Now

The trend of dwindling numbers of solo and small-group oncologists has been occurring "more rapidly since 2008," says Lenny Kalman, M.D., a medical oncologist with Advanced Medical Specialties and chair of the Government Relations and Public Policy Committee for US Oncology. "They are joining larger groups and networks, retiring from practice entirely and becoming employed by hospitals. The change in Medicare payment policy for office-administered drugs and its compounded effect on private-payer rates has undoubtedly contributed to this trend."

And the oncology community in particular has changed since the time covered in the study, says Kalman. For example, he tells *SPN*, "since 2008 there have been marked increases in the number of practices that decline to treat Medicare beneficiaries without secondary/supplemental coverage," as well as practices that send these patients to the hospital for chemotherapy infusions.

He notes that "both practices and hospitals [are] closing their outpatient chemotherapy infusion suites." Such changes, he contends, "are largely the result of the change to Medicare's payment policy for office-administered drugs."

But even though drug reimbursement decreased, "does that mean the physicians targeted in this report should pack their tents and refer every patient to a hospital outpatient clinic?" asks Sullivan. "No. They still need to survive, so they treat their patients in their offices to generate revenue through services and procedures and hopefully eke out a few profit dollars from drug revenue."

Both experts argue that the long-term view reveals a more dire situation. "Fewer and fewer physicians are entering these specialties based on declining earnings and the kind of stress associated with treating patients with severe chronic illness," Sullivan says.

And retirements of many oncologists “will lead to access care problems as the trend continues,” adds Kalman.

Contact Sullivan at wsullivan@specialtyRxsolutions.com and Kalman through Jennifer Horspool at (281) 863-6739. View the report at www.cms.gov/reports/downloads/Cheh_PartB_2009.pdf. ✧

Provenge’s Cost May Limit Use

continued from p. 1

“This is a new technology, a new way of approaching medicine, and it holds a lot of promise,” Riordan tells *SPN*.

According to the CDC, prostate cancer is the most common cancer among men in the U.S. In 2006 (the most recent year for which data are available), almost 30,000 men died of prostate cancer. A clinical trial showed that men lived an average of 4.1 months longer when treated with Provenge.

The therapy, which has been in development for almost 15 years, has an interesting back story. After an advisory panel voted for its approval in 2007, the FDA then declined to approve it and instead issued a complete response letter that requested more clinical studies. This provoked a firestorm of controversy, particularly among patient groups, and a couple of people on the panel who voted against approval claimed they received death threats and had to have security provided for them at an American Society of Clinical Oncology conference.

While noting that “scientifically, it is an important advance,” Lee Newcomer, M.D., senior vice president of oncology services for UnitedHealthcare, adds that “unfortunately, its clinical significance for today’s patient is minimal.”

The indication approved by the FDA is for a very narrow demographic, based on the groups studied in clinical trials, and plans tell *SPN* that they will use all of those factors in applying prior authorization to the drug. The indication for the drug is prostate cancer that is also:

- ◆ *Asymptomatic or minimally symptomatic,*
- ◆ *Metastatic to lymph nodes or bone* but not organs and
- ◆ *Hormone refractory.*

Most plans — including UCare — will put prior authorization on Provenge to “make sure that a patient matches the study population,” says Heaton.

United, says Newcomer, “will require clinical documentation that proves that the patient meets the same indications the FDA labeled.”

Helen Sherman, Pharm.D., senior director of pharmacy services and chief pharmacy officer at RegenceRx, The Regence Group’s not-for-profit PBM, tells *SPN* that because Provenge is referred to as a “therapeutic vaccine” — which is a product that stimulates the immune system to help it attack a disease — one of the first points the company had to address when determining its coverage policy is whether the therapy would fall under its definition of a “vaccine.” Based on the available information, “we did determine that it’s not a vaccine,” she says.

continued

How to Integrate FDA Risk Evaluation and Mitigation Strategy Requirements Into Formulary Management

- How can plans ensure that members have appropriate access to limited-distribution drugs under REMS programs?
- What steps should health plans and specialty pharmacies take to integrate REMS programs into their utilization management programs?
- How can the various stakeholders make sure they comply with patient privacy laws that could be compromised under REMS programs?
- What approach is needed when the FDA requires a REMS program for a drug that is already on the market?
- How can specialty pharmacies and PBMs leverage outcomes data from REMS efforts?

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Sherman also confirms that Regence, which serves more than 2.5 million members of Blue Cross and Blue Shield plans in Idaho, Oregon, Utah and Washington state, requires both of the following criteria:

(1) "Confirmation of metastatic prostate cancer... that would include histologically confirmed adenocarcinoma of the prostate and radiologic evidence of metastatic disease in the soft tissue and/or bone with evidence of progression at either of these sites," and

(2) Confirmation that the cancer is "hormone-refractory (also known as castrate-resistant or androgen-independent) [which] is defined as baseline testosterone levels <50 ng/mL."

After these criteria are confirmed, "up to three completed infusions (one course of therapy) would be considered medically necessary," Sherman says.

Additional Clinical Data Are Still Needed

But, she adds, these are "interim criteria" that are "based on the information available today, so it may be modified" later if needed. Information on the drug "is still evolving," she explains. "We currently are waiting for the dossier from the pharmaceutical manufacturer" to provide additional information on Provenge so it can "allow us to assess the quality and specific details of the trial(s)." She tells *SPN* that the plan has not gotten any feedback on when it might get this information.

In addition to prior authorization, some plans could put in place an edit to see whether the patient has tried Taxotere (docetaxel), which is also approved for metastatic, hormone-refractory prostate cancer and costs about one-third of the cost of Provenge for a treatment cycle, says Heaton. But because there are not any head-to-head data on the two drugs, information to support this approach doesn't exist.

He points out that an earlier study showed Provenge-treated people had a median survivorship of 25.9 months, compared to 21.4 months for the placebo group. Data from a clinical trial of Taxotere showed 18.9 months of median survival for Taxotere-treated people, compared with 16.5 months for the placebo group. So the men studied in the Provenge trial who received a placebo were already living an extra five months longer than the placebo group in the Taxotere trial. That begs the question of how comparable were the study populations, Heaton says. "Maybe they studied a less-sick population" for the Provenge trial, he says, noting that "it is a challenge to get an apples-to-apples comparison."

"We think it is not a good value," Newcomer tells *SPN*. "We are, however, legally required to cover a drug that has been approved by the FDA for the label recommendation."

And although many states have laws that require coverage of a cancer drug that is approved and/or has support in certain compendia or medical literature, if a patient meets precertification requirements, "I'll be surprised if payers balk at" covering Provenge, says Riordan.

While Provenge is not indicated for a specific age group, most prostate cancer occurs in older men, and most of the men studied in the clinical trials were older than 65. When you take into account this information, as well as the drug's indication, it is significant, contends Heaton, because "most of the people in this niche are in Medicare." For that reason, he says, many plans "are waiting to see what CMS does...CMS and the FDA are not always on the same page."

A CMS spokesperson tells *SPN* that the agency does not have a comment on what it will do as far as coverage or when some action could be expected other than to say that "there are no National or Local Coverage Determinations open for this treatment."

Asked if he's heard when CMS may make its stance public, Heaton says he hasn't "heard a peep." But "it's not exactly snuck up on them," he adds. "Someone there has probably thought about it, but the price tag probably surprised some people."

Factors May Impact Access Initially

Each Provenge dose is made using an individual patient's cells. Through leukapheresis, a patient's immune cells are collected about three days before the scheduled infusion, and then shipped to a manufacturing plant. There they are processed with a recombinant protein that activates the immune system, and then the product is shipped to a center for infusion in the person who provided the immune cells.

Because of the nature of the drug, it has very specific handling requirements. Its prescribing information notes that the drug will arrive in a box "with a specialty insulated polyurethane container inside" containing gel packs "to maintain the appropriate transportation and storage temperature." The information also specifically instructs physicians not to remove or open the insulated container until the drug is ready to be infused. Once the infusion bag is taken out of the container, it can be at room temperature for no more than three hours, and the bag cannot be put back into the container. There are also specific instructions to not administer the therapy until Dendreon has notified the physician of "patient identifiers, expiration date and time," and whether the drug has been approved for infusion or rejected based on sterility tests for contamination.

In addition, the drug is stable for a fairly short window of time before it expires, and opinions are mixed on whether this could impact uptake of the drug.

"Since it is a vaccine, it has a short expiration," says Thomas Hutson, D.O., Pharm.D., director of the genitourinary oncology program for Texas Oncology-Charles A. Sammons Cancer Center and co-chair of the genitourinary research committee for US Oncology. "There is a window of 20 hours to infuse the vaccine once it is made." Nevertheless, he tells *SPN*, this "will not affect utilization of the vaccine."

However, other sources who asked not to be identified by name tell *SPN* that this could impact patient access to the drug, particularly for those in small towns.

Another aspect that could limit uptake of Provenge is that the drug is now available through about 50 medical centers that participated in clinical trials for Provenge, although Dendreon has not said where these are located. In considering their coverage of Provenge, plans will need to take into account the location of these centers, says Heaton. "This will create an interesting scenario if a plan is certified in only one state or has an HMO-type network that doesn't extend three states away." Plans

will need to determine their potential patient population from a claims data research perspective, which "will be difficult," he says, and then determine where those people live.

In addition, for the first 12 months Provenge is on the market, only about 2,000 patients will be treated with the drug, says the company, which is working on increasing its manufacturing capacity. The company's New Jersey facility, which is operating at about a quarter of its capacity, currently is producing the drug. In a form 10-Q filed with the Securities and Exchange Commission on May 10, the company said it hopes to be at full capacity for that plant by the end of this year. Dendreon also has purchased facilities in California and Georgia on which it is working now that may be ready by the middle of 2011.

Contact Heaton at atheaton@ucare.org and Riordan at (781) 273-5480. Contact Newcomer through Lynne High at (952) 992-5708 and Sherman through Samantha Meese at (503) 225-5332. ✦

Will Provenge Price Tag Prompt Closer Look at Benefit Designs?

When the FDA recently approved the prostate cancer therapeutic vaccine Provenge (sipuleucel-T), it was hailed as a long-overdue move (see story, p. 1). But while speculation had put the drug's cost at around \$60,000, manufacturer Dendreon Corp. gave it a cost of \$93,000. That price tag may very well prompt further scrutiny of not just Provenge but also other high-cost therapies coming to market.

"With any drug that costs \$90,000, more and more people are going to assess what the real value is of the product," says Steve Avey, vice president of managed care at Partners Rx Management, LLC. If such drugs can influence a patient's prognosis, such as keeping them healthier longer and inducing long-term remission, the drugs will be used, he says. But in oncology, "the majority of drugs out there tend to be small improvements — two months, three months, four months."

Moving forward, Avey says, a "more targeted examination of these products" will mean that "not just an extra two, three or four months will be important, but also is there any opportunity it will cure [a person]? Is one person going to have an extra year of life?" Plans should "think about the patient going through that. This may be the only shot at a chance they have," says Avey, who also speaks from his own experience with cancer.

With Provenge, he points out, if there is an average 4.1 months of additional survival, then "some patients are getting better value."

And an average 4.1 months "is good for metastatic prostate cancer," maintains Matthew Riordan, manager at Putnam Associates, a pharmaceutical and biotechnology consulting firm.

In addition, Avey says, the side effects will be an issue. If a drug prolongs a person's life, but the side effects leave him or her so debilitated that he or she cannot enjoy the extra time, quality of life will have to be considered.

If more high-cost drugs continue to come onto the market, "pressures on financing these treatments will be extraordinary," says Helen Sherman, Pharm.D., senior director of pharmacy services and chief pharmacy officer at RegenceRx, The Regence Group's not-for-profit PBM. This could prompt some plans to put additional parameters around benefit contracts, she says. Most companies do not have cost-effectiveness information in their benefits now, but plans might begin to include a definition of cost benefit. For example, would an additional two weeks of survival be covered? What about an additional four weeks?

Contact Avey at steve.avey@partnersrx.com, Riordan at (781) 273-5480 and Sherman through Samantha Meese at (503) 225-5332.

NEWS BRIEFS

◆ **BioScrip, Inc. posted a first-quarter 2010 net loss of \$7.2 million, or 18 cents per share, down from net income of \$3.3 million, or 8 cents per share, for the year-ago period.** Revenues were \$335.1 million, compared with \$325.7 million, and the company attributed the decline to the acquisition of Critical Homecare Solutions (*SPN 2/10, p. 1*) and bad debt expense from the Medicare Part B Competitive Acquisition Program, which was postponed at the end of 2008 (*SPN 12/08, p. 1*). In other BioScrip news, the company is purchasing the assets of drugstore.com's pharmacy business, DS Pharmacy, for \$10.9 million. Visit www.bioscrip.com.

◆ **Diplomat Specialty Pharmacy has partnered with Southwest Oncology Network (SWON) to create an oral oncolytic management program for practices.** SWON-Rx is a comprehensive support program aimed at helping SWON members — 65 oncology practices with about 272 oncologists — attain the best clinical results for their patients. Members will also have access to Diplomat's Oncology Navigator program. Contact Diplomat's Kathy Karns at (810) 720-4452.

◆ **Consulting firm Therigy, LLC, will provide a variety of specialty pharmacy services to Henry Ford Health System.** According to Therigy, it will help the system design its new specialty pharmacy and create a specialty pharmacy service model with an integrated therapy management solution. Contact Joseph Morse at (407) 992-8752.

◆ **Cancer Treatment Centers of America unveiled an agreement with CIGNA Corp. that gives millions of the plan's customers in-network access to more than 330 physicians at CTCA facilities.** The four affiliated treatment centers are in Chicago; Philadelphia; Tulsa, Okla.; and Phoenix. Contact CTCA's Kristin Schaner at (847) 342-6454.

◆ **The von Willebrand Disease therapy Wilate is now available in the U.S.,** says manufacturer Octapharma USA. Authorized distributors are ASD Specialty Healthcare; BDI Pharma, Inc.; BioCARE; FFF Enterprises; and Health Coalition Inc. The FDA approved the injectable in December (*SPN 12/09, p. 11*). Dosing is based on patient weight and severity of hemorrhage; the Average Wholesale Price is \$1.38/IU, according to the company. Visit www.wilateusa.com.

◆ **UnitedHealthcare is offering at-home health screening tests through its corporate wellness programs for self-funded employers.** The kits are developed by BioIQ and come with instructions on how to collect and mail a blood sample to a certified lab. The launch comes after a pilot program last year in Washington state that involved more than 80 companies. According to United, that pilot helped identify about 10% of employees with high cholesterol and 4% with elevated indicators for diabetes. Visit www.uhc.com and www.bioiq.com.

◆ **Sen. Sheldon Whitehouse (D-R.I.) introduced S. 3320, the Pancreatic Cancer Research and Education Act, on May 6.** The legislation aims to reduce mortality among people with pancreatic cancer through advancing research and increasing awareness about the disease, which has a 5% five-year survival rate. The bill was referred to the Senate Committee on Health, Education, Labor, and Pensions. S. 3320 is the companion bill to H.R. 745, which Reps. Anna Eshoo (D-Calif.) and Ginny Brown-Waite (R-Fla.) introduced in January 2009. View the bill at thomas.loc.gov.

◆ **The FDA is reviewing the safety of gonadotropin-releasing hormone (GnRH) agonists, which are used mainly in the treatment of prostate cancer.** The agency is trying to determine whether the therapies could lead to diabetes, heart attack, stroke and sudden death. It says physicians should be aware of possible risks and monitor patients. Visit www.fda.gov.

◆ **PEOPLE ON THE MOVE:** Specialty pharmacy provider Axiom Healthcare Pharmacy named **Gerry Dabkowski** vice president of business development. He was previously area vice president of managed care at Accredo Health, Inc....President Obama appointed **Harold Varmus, M.D.**, director of the National Cancer Institute. He was previously president and CEO of Memorial Sloan Kettering Cancer Center....Specialty pharmacy consulting firm Therigy, LLC, named **Todd Cooperman, Pharm.D.**, director of research and development. He was previously clinical program manager for specialty and clinical rules engineer at CIGNA HealthCare....Walgreen Co. named **Cheryl Pegus, M.D.**, to the new position of chief medical officer. She was previously general manager and chief medical officer for SymCare Personalized Health Solutions, Inc.

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