

# SPECIALTY PHARMACY NEWS

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

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Go to [www.AISHealth.com](http://www.AISHealth.com) for a 10-page summary of the health reform bill passed by the U.S. House on November 7.

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## Keep Tabs on Oral Oncology Drugs, Which Are Living Up to Hype of Escalating Growth

As a rapidly growing number of cancer drugs flood the market, industry experts are advising payers to keep close track of oral oncolytics, which so far have lived up to the hype around increased spending and utilization. The high costs associated with oral oncology drugs have led to difficult cost-based treatment decisions for payers and health care providers, as some are scrutinizing the cost of therapy versus the survival benefits.

According to Medco Health Solutions, Inc., cancer drugs are on track to become the largest drivers of specialty drug spending. For the first time, cancer treatments accounted for 5% of Medco's overall drug spending in the first half of 2009, as spending increased by 15.1% last year, making them the third-largest contributors to the rise in specialty drug spending after medications for autoimmune conditions and multiple sclerosis. And between 2009 and 2011, these drugs are projected to account for 9% of all prescription pharmaceutical spending growth, reaching worldwide sales of \$80 billion by 2012.

*continued on p. 10*

## CMS Reverses Oct. 1 Avastin Code Change, But Three-Month Delay Could Prove Costly

Following a CMS code change to a drug often used off label for the treatment of an eye disease, protests from ophthalmologists and at least one congressman resulted in a reversal of that decision. But the subsequent change to Genentech, Inc.'s Avastin (bevacizumab) won't happen until the originally revised code has been in place for three months, and that delay could carry a high price tag.

The drop in reimbursement for the new Healthcare Common Procedure Coding System (HCPCS) code could prompt ophthalmologists using the therapy to switch to another Genentech drug, Lucentis (ranibizumab). Ophthalmologists contend that the drugs are equally effective, and early data from a head-to-head trial support this contention (see story, p. 3). But Lucentis is about 20 times more expensive.

CMS reimburses doctors \$2,029 for a dose of Lucentis, which means they pocket about \$120 per dose. A dose of Avastin costs retinal specialists \$20 to \$50. Prior to Oct. 1, CMS reimbursed Avastin for ophthalmologic use at about \$50 per dose. Now, up until the end of the year, this reimbursement has dropped to about \$7.20.

In September, CMS said that Avastin for ophthalmologic use would have its own HCPCS code, Q2024, starting Oct. 1. However, after receiving feedback from ophthalmologists, as well as others, CMS has said it will replace Q2024 with a new HCPCS C code with the same descriptor as Q2024. In addition, it says, ophthalmologists can revert to their previous billing practices. But neither of these changes will take effect until Jan. 1. Ellen Griffith, a spokesperson for CMS, confirms to SPN that CMS will be replacing the temporary code on Jan. 1. The current information on the new C code can be found in CMS's outpatient prospective payment system rule, she adds.

*continued*

In an Oct. 9 letter to CMS Acting Administrator Charlene Frizzera, Sen. Herb Kohl (D-WI) says about half of ophthalmologists and retinal specialists use Avastin off label. He notes that Lucentis "is costing Medicare more than a billion dollars a year in federal reimbursements." The reimbursement drop "has the potential to cost Medicare substantial sums as physicians switch to the \$2,000 a treatment cost for Lucentis," says Kohl, chairman of the Senate Special Committee on Aging. Bill Rich, M.D., medical director for health policy at the American Academy of Ophthalmology (AAO), says that CMS could potentially pay out an additional \$1.5 billion a year if doctors switched from Avastin to Lucentis.

The AAO says the initial decision has had a "huge impact" on ophthalmologists and patients. CMS's decision to establish the initial code "was well meaning but has had enormous unintended consequences," contends Rich. Ophthalmologic use of Avastin in the outpatient setting represents only about 5% of its overall use, while 95% occurs in physician offices, he says. Ultimately,

though, "We don't care how it started," says Rich. "We just want to make it right and get it back to where it was."

Media reports contend that some ophthalmologists have already switched patients from Avastin to Lucentis so that they won't lose money. Rich tells *SPN* that the academy has heard of "a couple" eye specialists who have switched to Lucentis. While the AAO does not have data on the number of physicians who have changed therapies, "our understanding is that it is very small," he says. But ophthalmologists who continue to administer Avastin "are losing about \$33 for every dose" of the drug, says Rich. In contrast, ophthalmologists who administer Lucentis are receiving about \$120 per dose, he explains.

Switching patients from Avastin to Lucentis also means that patients must make higher copayments. For this reason, says Rich, who is also in private practice at Northern Virginia Ophthalmology Associates, ophthalmologists transitioning patients "have gotten tremendous pushback" for this decision. Patients previously responsible for \$8 to \$10 copays with Avastin are now facing a \$400 copay for Lucentis.

### CMS Is Urged to Apply Change Retroactively

The AAO has said it would like CMS to apply the correction retroactively to Oct. 1. A CMS source who asked not to be identified says, however, that this is "very difficult" to do. Rich notes that CMS has allowed providers to submit claims retroactively before in similar situations. "Operationally it's been done," he says. "But I'm not sure how complicated it is." The AAO has advised its members to keep doing what they had been doing with respect to Avastin use before Oct. 1. Meanwhile, the AAO, the American Society of Retina Specialists, the Macula Society and the Retina Society are working to allow retroactive payments. As of *SPN* press time, there had been no word from CMS on how the change will be implemented or whether it would be retroactive.

The FDA approved Lucentis for wet age-related macular degeneration (AMD) in June 2006 (*SPN* 8/06, p. 4). At that time, there were only a handful of therapies for that condition available. But one of the most-used drugs at the time was Avastin, of which Lucentis is a modified form. First on the U.S. market in 2004, Avastin was approved for only colorectal cancer when the FDA approved Lucentis. Ophthalmologists, however, would obtain Avastin from compounding pharmacies, which would divide the vials into smaller, sterilized doses to treat wet AMD patients. This meant that Avastin, which cost about \$4,400 for a vial, could be administered off label to this patient population at a cost somewhere in the range of \$20 to \$50 per dose. When Lucentis came onto the market, it boasted a price tag of around \$2,000 per

**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](http://www.AISHealth.com).

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dose. At that point, says Rich, Lucentis had about a 45% to 55% market share. But now, Avastin has 60% of the market share for macular degeneration, he says. It should say something about the safety and efficacy of Avastin for this indication, he says, when ophthalmologists have a huge financial motivation to use Lucentis, but Avastin's market share has increased to this level. He adds that most of the therapies ophthalmologists use are off label, except for conditions such as glaucoma, pink eye and allergies. And NIH-sponsored randomized clinical trials involve drugs used off label as well, he points out. "This is what we do," he says. He adds that commercial payers do reimburse for this use of Avastin.

This is not the first time that Avastin's ophthalmologic use has been at issue. Genentech, now a Roche subsidiary, tried to modify Avastin's distribution in late 2007, citing safety concerns over its sterility when repackaged. The firm said that it would not allow compounding pharmacies to purchase the product directly from wholesalers, although it would still allow physicians and hospital pharmacies to purchase it (*SPN 11/07, p. 12*). But following an outcry from ophthalmologists, as well as from Kohl, the company said it would allow physicians to purchase the drug directly from authorized distributors, which could ship to a location designated by the physician, including compounding pharmacies (*SPN 1/08, p. 12*).

### Genentech Was Not Involved in Change

In his most recent letter to CMS, Kohl says he is "disturbed to learn from members of the medical eye care community that Genentech may have communicated directly with CMS officials about this proposed coding change, reportedly suggesting that CMS was overpaying for the small amounts of Avastin being used off-label for intraocular treatments." Griffith, however, says that "CMS did not have any discussions with Genentech about the coding change that went into effect October 1. The Q-code was created during a routine update to our HCPCS coding system, and the payment rate for the Q code was based on the manufacturer's average sales price for bevacizumab."

Genentech spokesperson Nikki Levy also tells *SPN* that "Genentech had no involvement in the decision by...CMS to create a product-specific temporary Q code for Avastin or to reverse its decision. Genentech believes that people should have access to the medicines their doctors feel are most appropriate for them."

The code-change news isn't bad for all stakeholders. "Genentech will get a nice unexpected year-end boost to their Lucentis sales because of the delay," points out Bill Sullivan, principal consultant with Specialty Pharmacy Solutions, LLC.

Contact Rich at [hyasxa@aol.com](mailto:hyasxa@aol.com) and the AAO's governmental affairs division at (202) 737-7061. Visit the Genentech Web site at [www.gene.com](http://www.gene.com). View the *MLN Matters* article on the addition of the code at [www.cms.hhs.gov/MLNMattersArticles/downloads/MM6594.pdf](http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6594.pdf). View the information on the C code at [www.cms.hhs.gov/HospitalOutpatientPPS](http://www.cms.hhs.gov/HospitalOutpatientPPS) and Kohl's letter at [www.aging.senate.gov/letters/cmsavastinoc2009.pdf](http://www.aging.senate.gov/letters/cmsavastinoc2009.pdf). ↵

## Early Study Results Show Drugs' Efficacy Is Similar in Wet AMD

A drug that is used off label for the treatment of wet age-related macular degeneration (AMD) is just as effective as a drug approved for the disease, according to early results of a clinical trial. But what may be the most important take-away is that the off-label drug costs approximately 20 times less per dose than the other does.

The therapies in question are both manufactured by Genentech, Inc.: Avastin (bevacizumab) and Lucentis (ranibizumab), which is a modified form of Avastin. Before Lucentis came onto the marketplace in summer 2006, ophthalmologists would use Avastin, a cancer therapy, to treat wet AMD, a disease that damages the macula, which is the part of the retina responsible for central vision. It is the most common cause of vision loss for people 55 and older. According to the National Institutes of Health (NIH), almost 2 million Americans suffer visual

### Genentech Confirms It Is Conducting Lucentis Sampling Pilot

Genentech spokesperson Nikki Levy confirms to *SPN* that the manufacturer is conducting a six-month Lucentis sampling pilot in three markets. "The sampling pilot program is designed to help retinal specialists try Lucentis on new wet AMD [i.e., age-related macular degeneration] patients to see if it is right for them. Additionally, samples may also assist retinal specialists in treating appropriate newly diagnosed wet AMD patients on the same day." The three markets were geographical areas that "met specific needs to properly test the pilot's functionality," she says. "There were a number of objective factors considered in the allocation model." She adds that the company "reserves the right at its sole discretion to modify the sampling program as we progress through the pilot. We will evaluate a national launch at the conclusion of the sampling pilot."

Visit the Genentech Web site at [www.gene.com](http://www.gene.com).

impairment due to wet AMD, and more than 7 million are at increased risk of vision loss from the condition.

But even after Lucentis became available, many ophthalmologists have continued to use Avastin off label for this indication. One reason is they claim that both drugs are equally effective, although there is a risk of infection because of the compounding required for Avastin. In addition, while Lucentis costs about \$2,000 per dose, compounding pharmacies could take a vial of Avastin and split it up into smaller doses for wet AMD treatments that would cost about \$20 to \$50 each (see story, p. 1).

In February 2008, the National Eye Institute of the National Institutes of Health (NIH) said it was starting a clinical trial of 1,200 patients at 47 centers around the U.S. comparing the safety and effectiveness of Lucentis and Avastin in the treatment of wet AMD (*SPN 3/08, p. 12*). Genentech, now a Roche subsidiary, is not participating in the trial.

### Study Results Could Improve Care, Save Money

According to NIH, "Avastin is thought to remain in the eye longer than Lucentis and therefore possibly allow for less frequent injections." The agency said that it "hoped the results of this study will improve the treatment of wet AMD." It also said that fewer treatments "without compromising effectiveness" would "produce a potential cost savings."

According to an *American Journal of Ophthalmology* article published online Oct. 5, early outcomes of a head-to-head, randomized, double-masked, prospective trial at the Boston Veterans Affairs Healthcare System "show no difference in efficacy between the two treatments for choroidal neovascularization in the treatment of age-related macular degeneration." The article also notes that because the data were based on 20 patients, more studies with larger sample sizes are needed before statistical significance can be established.

Although the trial is ongoing, Bill Rich, M.D., medical director for health policy at the American Academy of Ophthalmology, points out that if there were any safety issues — "which we never expected to find," he says — there is a safety data monitoring group that observes the trial on a continual basis. That group, he says, would have stepped in at the sign of any problems.

"This is the first really head-to-head trial the government has conducted," says Rich, who notes that even clinical trial policy had to change in order for this trial to happen. In addition, he says, "this is the first real example of comparative effectiveness" research.

Complete study results are expected in 2011.

View the *American Journal of Ophthalmology* article at [www.ajo.com](http://www.ajo.com). View the NIH press release at [www.nih.gov/news/health/feb2008/nei-22.htm](http://www.nih.gov/news/health/feb2008/nei-22.htm). ✦

## Boosted by Wider Product Lines, Allion Agrees to Be Purchased

Allion Healthcare, Inc., which went public in 2005, said last month that it has agreed to be purchased by private-equity group H.I.G. Capital, LLC. Industry experts contend that Allion's decision is wise, and they point to the specialty pharmacy services provider's 2008 purchase of another specialty company as having a positive impact on the new planned transaction.

The new deal is valued at \$278 million, including the assumption of about \$79 million in debt. It is expected to close in the first quarter of 2010.

Through its MOMSParmacy, Allion provides specialty pharmacy services to HIV/AIDS patients. It also furnishes other specialty medications and services to chronically ill patients. In its most recent Form 10-Q filed with the Securities and Exchange Commission (SEC) Nov. 9, the company notes that since the beginning of 2003, it has acquired seven specialty pharmacies in California and two in New York. But it was the acquisition last year of Biomed America, Inc. that really was noteworthy, says Chuck Gaetano, managing director of The Braff Group, a health care mergers and acquisitions company. Allion broadened its focus to therapies including intravenous immune globulin and clotting factor for hemophilia in 2008 when it acquired Biomed for \$117.8 million — \$99.4 million in cash and stock, and the assumption of \$18.6 million in debt (*SPN 4/08, p. 6*). Following that purchase, the company operated its business in two segments: the original Allion as Specialty HIV and Biomed as Specialty Infusion.

"Allion's overall financial picture and corporate worth improved by acquiring Biomed," contends Bill Sullivan, principal consultant with Specialty Pharmacy Solutions, LLC. "It diversified their product portfolio and was financially accretive. In short, it made Allion a more attractive/stable acquisition candidate."

### Company First Considered Sale in January

In its Schedule 14A filed with the SEC on Nov. 2, Allion notes that "in light of market, economic, competitive, regulatory and other conditions and developments," the company's board of directors began exploring the possible sale of the company this past January. Through Raymond James Health Care Investment Banking Group, the company executed confidentiality agreements with 51 potential buyers in February. Initial proposals from various companies included prices ranging from \$4.25 to \$6 per share, with a later proposal offering between \$7 and \$7.50 per share. By May, however, H.I.G. was the only remaining potential buyer. The 14A document details the price-per-share negotiations in which the companies engaged. In H.I.G.'s initial letter of intent in June, it offered \$5.50 per share. But after requesting that

H.I.G. increase the price and faced with an offer of only \$6 per share, Allion decided to terminate negotiations in early September. The companies resumed negotiations at H.I.G.'s request a couple of weeks later, and Allion disclosed the planned deal on Oct. 18.

A handful of law firms and an investor advocacy group have said they have begun investigations of the deal. They charge that the \$6.60 per share that Allion stockholders are slated to receive from the transaction is unfair to investors. They point out that Allion shares traded at \$7.74 as recently as July 31, the company's book value is \$6.62 per share, and \$9 per share is the median price target set by securities analysts for the company's stock.

According to Allion's 14A document, "Both the Special Committee and our Board of Directors have determined that the merger agreement and the merger are fair to and in the best interest of the Company and our affiliated stockholders."

The agreed-upon amount "seems like a pretty good price," Gaetano says. According to Sullivan, "There have been thousands of deals that shareholders have thought were undervalued."

He adds that "H.I.G. would not have pulled the trigger unless they thought [the price was reasonable], and they have a small army of Ivy League MBAs making those kinds of evaluations."

*continued*

## Highlights of House-Passed Health Reform Bill

The following are some provisions in the Affordable Health Care for America Act (H.R. 3962) that may be of interest to Specialty Pharmacy News readers. The U.S. House of Representatives passed the bill Nov. 7.

### Insurance Reforms:

- ◆ **Insurance reforms:** Bans insurance rating using health status or pre-existing conditions. Bans annual and lifetime limits on coverage of medical expenses.
- ◆ **Benefits:** Limits annual out-of-pocket expenses to \$5,000 for an individual and \$10,000 for a family, with lower levels for lower- and middle-income families.
- ◆ **Home health study:** The Medicare Payment Advisory Commission will conduct a study on variation in Medicare margins among home health agencies.
- ◆ **Telehealth:** Extends Medicare's telehealth benefit to beneficiaries receiving care at freestanding dialysis centers.

### Medicaid:

- ◆ **Coverage for HIV-positive individuals:** State Medicaid programs will cover low-income individuals through Dec. 31, 2013. After that, coverage will be available through the Health Insurance Exchange or Medicaid.
- ◆ **Increasing prescription drug rebates:** Increases the minimum percentage rebate on brand drugs to 23.1% of average manufacturer price and gives rebates to new formulations of brand drugs.

### Medicare Part B:

- ◆ **Cost sharing for preventive services:** Eliminates deductibles and copayments for preventive services.
- ◆ **Improved access to vaccines:** Covers all vaccines under Part B rather than Part D.
- ◆ **Extends months of coverage of immunosuppressive drugs for kidney transplant patients:** Ends the current

36-month limitation on coverage for patients who would lose this coverage on or after Jan. 1, 2012.

- ◆ **Durable medical equipment in Medicare:** Exempts some pharmacies from the surety-bond requirement and the accreditation requirement to sell diabetic testing supplies and some other items.

### Medicare Part D:

- ◆ **Medicare drug benefit:** Eliminates the "doughnut hole" coverage gap over time. Also provides 50% discount for enrollees within the doughnut hole and restores manufacturer rebates for Part D drugs used by Medicare-Medicaid dual eligibles and low-income subsidy eligibles.

### Other:

- ◆ **Follow-on biologics:** Creates a pathway for the FDA to approve biosimilars and offers 12 years of exclusivity for the reference product from when it was licensed.
- ◆ **Comparative effectiveness research (CER):** Creates a new center at the Agency for Healthcare Research and Quality to conduct CER. Subpopulations will be accounted for. An independent stakeholder commission will recommend research priorities. Neither the center nor the commission can mandate payment, coverage or reimbursement policies.

### Public Health and Workforce Development:

- ◆ **Expanded participation in 340B program:** Extends outpatient drug discounts to certain rural and other hospitals.

Access a link to a summary of the House bill at [www.AISHealth.com](http://www.AISHealth.com).

As of *SPN* press time, Allion had not announced the date for its shareholder vote. Shareholders with approximately 40% of Allion's shares have agreed to vote in favor of the merger.

The timing of the deal is good, says Sullivan. "The fact that Allion had not been able to achieve impressive growth in HIV pointed to the need to shake things up," he says. "The acquisition, probable access to new capital and external management expertise can be a good prescription for any company needing a boost." In addition, says Gaetano, health care "is not a very good industry to be [a] public [company] in" because of the intense scrutiny health care firms receive. Sullivan agrees. "Being publicly held places a lot of limitations on a company like Allion," he says.

Once the deal is final, Allion could continue to expand its product lines, says Gaetano, perhaps in an area such as growth hormone. Sullivan tells *SPN* that potential developments could include "horizontal and/or vertical integrations through acquisitions, mergers, investment in new technology, marketing, staffing, etc. Or they could be simply looking to spruce up the place, develop a stronger EBITDA [i.e., earnings before interest, taxes, depreciation and amortization] line and sell to one of the big specialty pharmacies for a nice profit."

Contact Gaetano at (888) 723-9263 and Sullivan at wsullivan@specialtyrxsolutions.com. ✧

## REMS Benefit From Specialty Pharmacies' Core Competencies

With the FDA's recent release of draft guidance for a risk evaluation and mitigation strategy (REMS), many pharmaceutical companies may be concerned that the requirements could mean it will take much longer for a drug to reach the marketplace than it now does (see story, p. 9). However, if pharma firms work with specialty pharmacies on a REMS, this collaboration can produce value for manufacturers, as well as health plans, contend sources at specialty pharmacies.

According to the FDA's Web site, the agency had approved 89 REMS as of Oct. 30. Of these, 15 were for biologics, including Cimzia (certolizumab pegol), Enbrel (etanercept), Extavia (interferon beta-1b) and Nplate (romiplostim). Steve Russek, chief clinical officer of Accredo Health Group, a subsidiary of Medco Health Solutions, Inc., says that on the specialty side with biologics and orphan drugs, there is a higher percentage of REMS, perhaps in the 30% to 40% range, than with non-specialty drugs. Craig Kephart, president and CEO of Centric Health Resources, Inc., tells *SPN* that he expects the FDA will exert "more regulatory control" and begin requiring even more REMS overall. "In exchange for

allowing drugs to come to market faster, the FDA is layering on REMS," he says. "Almost everything in the future will have some component of a REMS."

There are two types of REMS, says Russek. About two-thirds of existing REMS have only a medication guide that provides more safety information, and others include Elements to Assure Safe Use (ETASU), which is incorporated when a drug may have a serious adverse event. An ETASU would include a goal or goals to mitigate the risk of the event, such as requiring providers to enroll patients in a registry and health care professionals to check lab values before dispensing a drug.

### Requirements Are Routine for Companies

For many reasons, "the specialty pharmacy platform is the only logical choice" to execute a REMS, Kephart says. ETASUs "can be very complicated and require tight communication with physicians and patients, usually every 30 days," Russek says. "This is what we do, so this is an extension of the specialty pharmacy model" in that these companies monitor patients to ensure these people are not at risk. He adds that Accredo includes information from the medication guides, such as signs of infection or depression, as part of its patient counseling. "We don't want to scare people, but we want them to be aware there could be a reaction," he says.

Russek says that manufacturers can contract with a hub, through which anyone receiving a particular drug must go. The hub can then refer the patient to a specialty pharmacy. Proherant Health, Inc. is Accredo's hub, but it is a separate organization from the specialty pharmacy, he explains, noting that Proherant may have patients come through who may be patients of an Accredo competitor. When a REMS requires patient registration, the hub maintains this information. The specialty pharmacy also reports patient data to the hub.

With an increasing focus on personalized medicine, manufacturers will find their markets growing smaller, Kephart asserts. Plus, he says, "it's a pretty fair bet that" the smaller the patient population and clinical trial size, "the greater the REMS requirement will be." In addition, the "margin model," in which specialty pharmacies make their money off profit margins for drugs, "is not going to survive," so these companies need to offer value that plans and manufacturers will pay for, he says. "Specialty pharmacies have the ability to control the pedigree of the product and the ability to control the patient experience," he says. "With the feds holding pharma manufacturers responsible for what happens in the marketplace, REMS are a way to mitigate" this risk, he says. These companies should design a distribution strategy that has layered in a REMS, he says. In fact, many manufacturers are already working with specialty pharmacies such as Accredo and

Centric before their drugs hit the marketplace to design an effective REMS.

"We've become more of a consultant to pharma companies," asserts Nick Calla, vice president of trade relations for Walgreens Specialty Pharmacy. "With the FDA putting a lot more requirements on products as they come to market... we have less of a vendor-client relationship than a partnership."

According to Kephart, independent specialty pharmacies that "focus less on volume and more on high touch" have a "great opportunity" to realize success on a national level by leveraging REMS capabilities. Many larger specialty pharmacies, he says, have invested a lot in automation and tend to have more mail-order distribution processes for numerous disease states that have larger patient populations. The challenge for pharmacies managing drugs with REMS in conditions such as multiple sclerosis or rheumatoid arthritis is those larger patient populations, he says. While Kephart points out that he's not saying larger specialty pharmacies cannot do REMS well or that they provide bad care, he maintains that bigger numbers of patients mean the greater potential for "more points of disconnect and a greater chance of failure. Every time they hand a patient off, that is a potential point of failure."

Health management programs provide patient education, assessment and intervention and help get patients "into positive pathways for care," says Kephart (*SPN 11/08, p. 9*). As an example, he cites pemphigus, a group of rare autoimmune blistering diseases impacting the skin and/or mucous membranes. Patients may take biologics as well as high-dose oral steroids, which can have side effects such as high blood pressure, diabetes and bone mass

loss. So a REMS program for one of these biologics could include, for instance, speaking with patients about having a bone scan annually and checking their blood sugar levels regularly. "This has an economic value," contends Kephart, if a company can demonstrate that it helped prevent diabetes in a percentage of a patient population. In addition, many biologics that have smaller patient populations do not have a lot of data by the time they hit the marketplace. Data collection through a REMS could be good for the manufacturer if concerns about a drug prove to be overblown when the drug's effects are not as bad or as widespread as initial perceptions.

If a company has to have a REMS program anyway, it doesn't cost that much more, Kephart says, to build in ways to determine outcomes such as whether the overall management approach helps improve quality of life and reduce hospitalizations. That way, if a company can "measure, capture and claim these outcomes as part of your value proposition, you can say that my program generates this value," he contends.

Kephart says he encourages manufacturers to "get out of the mindset of thinking about only the therapeutic impact of their drug." When companies can demonstrate the economic value of their programs, this "creates a win for every member of the value chain," he maintains. Manufacturers win because they can justify their costs, payers win because the program will produce better outcomes, and patients win because they get a better quality of life.

Although "REMS are good and something the industry needs," one challenge with a REMS is its potential impact on cost to the health care delivery system, points

## Strategies to Manage Specialty Drugs in the Medical Benefit

- How do the big challenges with traditional pharmacy and medical benefit designs influence prescribing of high-cost oral and injectable medications?
- What are the major advantages of managing drugs in both the pharmacy and medical benefits? What are the major disadvantages?
- What were the implementation processes for the companies?
- How were the programs designed? What were their goals?
- Which strategies employed worked most effectively? Which were not successful?
- What outcomes did the companies experience?
- What are some of the issues that still remain?

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out Russek. Such programs certainly add administration not just to specialty pharmacies but also to physicians, manufacturers and health plans. But, he says, considering the severe side effects of some of these drugs, including death, the key question is, "Do the extra safety measures potentially decrease costs tied to emergency room visits and hospitalizations?"

Beyond the safety aspects of patients not complying with a REMS, companies will now face some fairly pricey penalties for noncompliance. The agency will first look at the manufacturer if there's a problem, says Calla, but the specialty pharmacy will be in the crosshairs next. So if

specialty pharmacies commit to working with a manufacturer on a REMS, they must ensure that they adhere to all of the requirements.

Health plans also have a role to play with REMS, contends Russek. By placing prior authorization on these drugs, payers can "make sure the drugs are being used by the patient populations that need them," he says. This could include not allowing a drug's use as a first-line therapy if there are other therapies available, he explains.

Ultimately, managing a REMS "is becoming a core competency of specialty pharmacies," adds Calla. In fact, he says, "the ability to handle these...figures very

## NEW FDA SPECIALTY DRUG APPROVALS

◆ **On Oct. 12, the FDA approved Berinert (C1-esterase inhibitor, human) for the treatment of acute abdominal or facial attacks of hereditary angioedema in adults and adolescents.** Manufacturer CSL Behring says the drug is the first and only therapy to be approved for this indication in the U.S. A spokesperson says CSL Behring expects the injectable to be available in the U.S. by the end of the year. She says she cannot disclose the drug's price. Visit [www.berinert.com](http://www.berinert.com).

◆ **On Oct. 16, the FDA granted another indication for the sanofi-aventis drug Elitek (rasburicase).** Initially approved in 2002 to manage plasma uric acid levels in children receiving anti-cancer treatment who were at risk for tumor lysis syndrome, the infusible now is indicated for adults with leukemia, lymphoma and solid tumor malignancies at risk of TLS. A sanofi-aventis spokesperson says that the drug is administered once daily for up to five days, and the dosage is based on patient weight. The wholesale list price per day for a 150-pound adult treated with 13.64 mg daily for five days is \$4,500, she says. Visit [www.elitekinfo.com](http://www.elitekinfo.com).

◆ **On Oct. 19, the FDA approved Votrient (pazopanib) for the treatment of advanced renal cell carcinoma.** GlaxoSmithKline (GSK) says the oral drug is expected to be available this month. It is the sixth drug to be approved for kidney cancer since 2005. GSK did not respond to a request by *SPN* for pricing information. Visit [http://us.gsk.com/products/assets/us\\_votrient.pdf](http://us.gsk.com/products/assets/us_votrient.pdf).

◆ **On Oct. 19, the FDA approved Prolastin-C (Alpha 1-proteinase inhibitor [human]) for the treatment of Alpha 1-antitrypsin deficiency.** The Talecris Biotherapeutics infusible is a more concentrated version of the company's Prolastin, which came onto the U.S. marketplace in February 1988. A Talecris spokesperson says

that physicians will transition patients from Prolastin to Prolastin-C, which is expected to be available in the first half of 2010. She did not have pricing information available. According to 2005 data from Fallon Community Health Plan, based on a price of \$175 for 500 mg of Prolastin, the monthly cost would be \$5,880, with an annual cost of \$76,440. Visit [www.prolastin.com](http://www.prolastin.com).

◆ **On Oct. 26, the FDA approved Arzerra (ofatumumab) for the treatment of chronic lymphocytic leukemia that is refractory to fludarabine and alemtuzumab.** Manufactured by GSK and Genmab A/S, the infusible received accelerated approval. GSK did not respond to a request for information. At the time of approval, GSK said the drug would probably be available "in the coming weeks." Visit [http://us.gsk.com/products/assets/us\\_arzerra.pdf](http://us.gsk.com/products/assets/us_arzerra.pdf).

◆ **On Oct. 31, the FDA granted an additional indication to Amylin Pharmaceuticals, Inc.'s Byetta (exenatide) for use as a stand-alone therapy in adults with type 2 diabetes.** The injectable was first approved in April 2005 (*SPN* 6/05, p. 8) for patients already taking other diabetes medications. The FDA also approved changes to the drug's prescribing information and label incorporating updated safety information. Six 10 mcg pens cost \$1,607.89 at [drugstore.com](http://drugstore.com). Visit [www.byetta.com](http://www.byetta.com).

◆ **On Nov. 5, the FDA approved Istodax (romidepsin) for the treatment of cutaneous T-cell lymphoma in patients who have received at least one prior systemic therapy.** Gloucester Pharmaceuticals says it expects the infusible to be available in January. MacDougall Biomedical Communications, listed as Gloucester's contact, did not respond to a request for information. Visit [www.istodax.com](http://www.istodax.com).

prominently" in manufacturers' requests for proposal (RFPs). "We are judged on our ability to adhere to REMS programs," he says, adding that even some health plans' RFPs already include information about REMS. At this point, the discussions are "not very robust, but plans are getting their arms around this, and it will grow," he maintains.

Contact Kephart at (866) 849-4481, Calla at (412) 325-6507 and Russek through Ann Smith at (201) 269-5984. ✧

## Fines Are Among Noteworthy Parts of Proposed REMS Guidance

Although the FDA has been requesting risk evaluation and mitigation strategy submissions for a couple of years now, it has just recently released the first draft guidance for a REMS. While there weren't any huge surprises in that Sept. 30 guidance, there were a few noteworthy aspects, industry sources tell *SPN*.

The FDA can require REMS with new drug applications (NDAs), abbreviated new drug applications (ANDAs) and biologics license applications (BLAs). According to the FDA's Web site, the agency had approved 89 REMS as of Oct. 30, 15 of which were BLAs, including PegIntron (peginterferon alfa-2b), Simponi (golimumab) and Stelara (ustekinumab). The Food and Drug Administration Amendments Act of 2007 (FDAAA) authorized the FDA to require a REMS as part of a drug application if the agency determined that it needed to ensure that the benefits of the drug outweighed the risks. Before the FDAAA, a risk minimization action plan (RiskMAP) was used when more stringent risk management strategies were needed beyond labeling and reporting requirements. The multiple sclerosis and Crohn's disease therapy Tysabri (natalizumab), for example, has a RiskMAP because of patients' risk of acquiring progressive multifocal leukoencephalopathy, a potentially fatal viral infection of the brain.

In 2005, the FDA issued guidance for RiskMAPs, much of which is similar to the issued REMS guidance as well as future REMS documents, according to the FDA. The REMS guidance notes that unless new safety information on an approved drug comes out, the RiskMAP guidance will still apply to products with an existing RiskMAP, as well as to drugs approved under ANDAs whose reference product has a RiskMAP. ANDAs that have a reference drug with a REMS likewise will be required to have a REMS with the same elements as the reference drug's.

Companies can voluntarily submit a REMS if they think it necessary, and those REMS will be subject to the same requirements as an FDA-required REMS.

The document offers guidance on the following:

- ◆ **Format and content of proposed REMS**, including supporting documentation;
- ◆ **Content of assessments and proposed modifications** of REMS already approved;
- ◆ **Identifiers to use on REMS documents**; and
- ◆ **Communications with the FDA about a REMS**.

The FDA noted that it will issue additional REMS guidance documents, but it did not give a timeline.

### FDA Means Business With Penalties

While the requirements for a REMS may seem onerous at first blush, this approach could allow a drug onto the marketplace when it might otherwise have posed too great of a safety risk without a REMS. The guidance is pretty much "what we really know already," says Nick Calla, vice president of trade relations for Walgreens Specialty Pharmacy. But there are some noteworthy aspects of it.

For one, the noncompliance penalties "give the FDA a lot of power" to enforce a REMS, says Steve Russek, chief clinical officer of Accredo Health Group, a Medco Health Solutions, Inc. subsidiary. The guidance proposes a minimum fine of \$250,000 per violation, up to \$1 million in a single proceeding for a person who violates a REMS requirement. If the violation continues for more than 30 days after FDA notification of the violation, the penalties double and then "continue to double for subsequent 30-day periods, up to \$1 million per period and \$10 million per proceeding," says the guidance. "I think we will see penalties handed out, and they'll be significant," says Calla.

The guidance also says that a REMS must state one or more overall goals of the program. "REMS goals should target the achievement of particular health outcomes or knowledge related to known safety risks and should be stated in a way that aims to achieve maximum risk reduction," it explains. Companies should "assume we need to measure everything," says Craig Kephart, president and CEO of Centric Health Resources, Inc. This means they'll need a way to quantify whether patients and physicians understand the information given to them, he says.

The guidance also gives a timetable for companies to submit assessment data. "Each timetable for submission of assessments of a REMS must at a minimum include assessments submitted by 18 months and by 3 years after the REMS is initially approved, and in the 7th year after the REMS is initially approved, with additional dates if more frequent assessments are necessary to ensure that the benefits of the drug continue to outweigh the risks," it says. "I'm glad to see this is not just a safety program with no one assessing" any outcomes, says Russek.

"This seems well thought out," he says. "The elements of the guidance...give the industry the flexibility to

work with the FDA. Different elements are brought into use depending on the drug." Because the manufacturer is responsible for a lot of documentation, "a specialty pharmacy becomes an important partner," he adds (see story, p. 6).

The guidance was published in the Oct. 1 *Federal Register*, and comments are due by Dec. 30. View the proposed guidance at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM184128.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM184128.pdf). View the RiskMAP guidance at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071616.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071616.pdf). View a list of approved REMS at [www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm). Contact Kephart at (866) 849-4481, Calla at (412) 325-6507 and Russek through Ann Smith at (201) 269-5984. ✧

## Oral Oncolytics Catch Up to Hype

*continued from p. 1*

Meanwhile, orals constituted approximately \$8 billion of the \$40 billion oncology drug market last year. And it's estimated that about 30% of the 800 new drugs in the pipeline for treatment of cancer are oral therapies, according to Medco's 2008 *Drug Trend Report*. Some oral oncology drugs in the pipeline include Amgen's motesanib for treating non-small cell lung cancer and Novartis' midostarin for the treatment of acute myeloid leukemia. Meanwhile, GlaxoSmithKline received FDA approval just last month for its kidney cancer drug Votrient (pazopanib).

"As more of these products come out, they're identifying different ways in which to target the cancer, so they're becoming more popular," Debbie Stern, vice president of consulting firm Rxperts, Inc., tells *SPN*. Stern has been tracking the shift from injectables to orals, and she maintains that patients previously untreated or sidelined may be willing to start oral therapy. "The expectation is that more oral drugs will be used due to patient preference and ease of administration." Other reasons for the shift from injectables to orals include the fact that oral cancer therapies have shown fewer side effects and that physician reimbursement for injectables and their administration has decreased.

Last year, health plans acknowledged that oral oncology drugs were achieving rapid growth, but were surprised by the fact that they weren't being prescribed as much as industry had expected (*SPN 10/08, p. 1*). Steve Miller, M.D., chief medical officer at Express Scripts, Inc., contends that this trend has changed and that oncology drugs have lived up to the hype around cost and utilization increases. "This growth is primarily made up by inflation and utilization and partly based on new drugs," he

tells *SPN*. "One of the drivers for this growth continues to be the oral oncology drugs."

Bill Sullivan, principal consultant with Specialty Pharmacy Solutions, LLC, says that health plans will have to be as creative as possible when managing drug benefits for oral oncolytics. "From a payer's perspective, this is one of the categories that's hardest for payers to put real constraints on because there's legislation out there that often prevents restriction or limited access to certain oncology drugs," he tells *SPN*. "Ultimately, all these drugs fit the same category, so the question becomes how do you differentiate one from the other unless it's very clearly a distinct difference from a clinical efficacy standpoint?"

According to Nick Opalich, specialty pharmacy consultant for Strategica Health Partners, patient survival rates are up overall because of new therapies on the market and advances in awareness and early detection. However, he agrees this is an "emotionally and ethically charged topic," and adds that the payer and physician communities have not been able to reach an agreement on what constitutes a survival benefit. "There are physicians who think a three-to-six-month survival is an advance," he says. "But the value of an additional six months of life is hard to quantify. It's priceless to the beneficiary most of the time, but difficult for the payers to underwrite and justify." He adds that some health plans are willing to consider different physician fee options and "will perhaps be aggressive in tying a higher professional fee to a definitive patient outcome, and together they'll define what a survival benefit should be."

## Patient Compliance Is Issue Even in Oncology

Patient compliance with oral therapies also remains a significant concern and one that payers will have to manage to keep cost down. "It is always fascinating to look at compliance and oncology drugs because you would think a person with cancer would be highly compliant with their drugs," Miller says.

But there are several reasons for why patients may not be compliant, including forgetfulness, the advent of side effects and exorbitant costs. According to Prime Therapeutics LLC, one in eight patients forgoes recommended cancer treatment due to high out-of-pocket cost.

Many of the newer classes of oral oncology drugs will require some form of therapy management that involves compliance and adherence initiatives on the part of health plans, Opalich says. "Because some local pharmacies don't have the operational support background to provide therapy management, little, if any, feedback is provided back to the physician or payer." He adds that payers have a huge incentive to monitor patient compliance because of the amount that oral oncology medications cost. "Let's face it, they don't want to spend money on expensive

drugs and have them wasted because of poor compliance. There is only so much money to go around, and no one wants to waste it." He suggests that payers should "work into their benefit structure reimbursement strategies to compensate for compliance and adherence, but tied to a definite positive patient outcome."

Medco has pharmacists and nurses in its specialty pharmacy who speak with patients to educate them about how to take their drugs and control their side effects, and also offer reminders to fill the prescription, according to Milayna Subar, M.D., national practice leader for Medco's Oncology Therapeutic Resource Center. "Medco is very focused on helping to prevent waste," she tells *SPN*. "For cancer patients, we have to be cognizant of how the patient is doing or how the tumor is doing.... So we would make sure for one cycle that the patient can tolerate it and the drug is being used before you dispense more."

Stern notes that other payers are looking at providing similar short-term medication supplies for the first fill, such as one or two weeks, rather than sending out a full month's supply of therapy. "It's kind of a test phase or initial trial period to see if the patient can tolerate the medication," Stern says. "Sometimes, the terminal stage of the patient's cancer is that they don't even finish the cycle, so there is a potential for waste."

Opalich says that many new oral oncology drugs have been managed through limited-distribution

agreements with pharmaceutical manufacturers. Thus far, payers have been a little slower to adopt a reimbursement scheme to measure compliance. However, he adds, "the ability to demonstrate outcomes through specific reporting and data channels will change the attitudes of the payers over time."

All experts agree that payers and specialty pharmacies will need to be proactive in developing management programs to support patients on oral therapies and ensure appropriate use.

"A good start would be near-real-time systems to link drug benefit use with medical benefit use, on the basis of claims received," Elan Rubinstein, principal of EB Rubinstein Associates, tells *SPN*. The problem, however, is that most physician office claims are submitted on a delayed basis, and the cancer site and laboratory results are not on the claims, which limits the payer's ability to know whether the prescribing of a certain drug was "in line with evidence-based medicine and guidelines."

Miller says health plans need to keep an eye on three key issues — comparative effectiveness research, the establishment of a regulatory pathway for follow-on biologics and the increased use of biomarkers. "We need a way to try to predict what patients will respond to what drugs," he says. For example, some plans recently added prior-authorization requirements for metastatic colorectal cancer patients to get the KRAS genetic test before taking drugs

### ***Physicians, Payers Disagree on Oral Oncolytics' Off-Label Use***

Off-label use is still rampant within the oral oncology segment, making reimbursement challenging for health plans that have to figure how they should pay for the treatments.

According to Prime Therapeutics LLC, nearly one in seven new prescriptions for tyrosine- and multi-kinase inhibitors — which represent one-third of oral cancer drug expenditures, with the most commonly used doses costing \$4,340 to \$8,920 per month's supply — was for an off-label use. With a prior authorization in place, Prime estimates health plans could save \$211,868 by reducing off-label use (*SPN* 9/09, p. 7).

Nick Opalich, specialty pharmacy consultant for Strategica Health Partners, says that many payers are increasingly utilizing prior-authorization restrictions to limit inappropriate use of these therapies. "Appropriate utilization management is the chief tool for payers and significantly impacts prescribing behavior through questioning." But he contends that off-label use of oral oncology drugs isn't as prevalent anymore. "Increased scrutiny, medical-necessity justification and

reimbursement re-engineering [have] reduced 'experimental' uses dramatically."

Bill Sullivan, principal consultant with Specialty Pharmacy Solutions, LLC, argues that off-label use has been beneficial in oncology. "Oncology isn't managed one drug at a time," he says. "It's managed as a protocol, which is usually a combination of drugs. And it's through that tweaking and adjusting a protocol for a particular stage of cancer to see which works best." He says it's necessary for oncologists to have substantial discretion to manage these drugs and make them work for the patients.

Therefore, he advises health plans to be proactive and develop a collegial approach in working with their oncology networks to introduce best practices and couple them with "more creative reimbursement programs for oncology that target results which ultimately may be a win-win for everybody."

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that work on only certain types of tumors (*SPN 3/09, p. 1*). In addition, Miller says, by increasing funding for comparative effectiveness research, "we will know protocols as to which drugs are most effective for patients, which will lead to lower costs and improved outcomes."

According to Stern, benefit design and utilization strategies should include mandatory specialty pharmacy distribution, cost share that is similar to other specialty drugs, prior authorization and specialty pharmacy-developed therapy management programs and dispensing packages to support unique requirements of orals.

She advises payers to pay attention to their cost share to see whether it is having any impact on utilization. "It doesn't help when patients have such high cost share that they're not getting their prescriptions filled," she says. "So be aware that this is happening and [that you're] not cost shifting too much."

For more information, contact Stern at (949) 788-2909, Opalich at nopalich@gmail.com, Sullivan at wsullivan@specialtyrxsolutions.com, Miller through Missy Britan at (202) 530-4531 and Subar through Ann Smith at (201) 269-5984. ✧

## NEWS BRIEFS

◆ **Allion Healthcare, Inc. reported third-quarter 2009 net income of \$3.2 million, or 11 cents per diluted share, compared with \$2.8 million, or 11 cents per diluted share, for the year-ago quarter.** The company said revenues were \$103 million, up from \$92 million. Visit [www.allionhealthcare.com](http://www.allionhealthcare.com).

◆ **BioScrip, Inc. posted third-quarter 2009 net income of \$5.7 million, or 14 cents per diluted share, up from \$1.4 million, or 4 cents per diluted share, for the year-ago period.** Revenues were \$333.5 million, compared with \$359.4 million. The company attributed the decline to the postponement of the Medicare Competitive Acquisition Program for Part B drugs (*SPN 12/08, p. 1*) and the termination of a UnitedHealth Group, Inc. contract. For more information, visit [www.bioscrip.com](http://www.bioscrip.com).

◆ **Diplomat Specialty Pharmacy says that Inland Empire Health Plan selected the company as the exclusive provider of specialty disease management services for certain IEHP members.** Diplomat will provide drugs and patient care services to IEHP members with rheumatoid arthritis, psoriasis and Crohn's disease starting Nov. 1. Contact Diplomat's Kathy Karns at (810) 720-4452.

◆ **Medco Health Solutions, Inc. says its contract with the Blue Cross and Blue Shield Association's Federal Employee Program for mail service and specialty pharmacy benefit management has been extended.** The agreement was initially for three years and has been extended one year, through Dec. 31, 2011. Visit [www.medcohealth.com](http://www.medcohealth.com).

◆ **Therigy Corp. has unveiled a specialty pharmacy Web application for pharmacies.** TherigySTM.com allows community, specialty and home infusion

pharmacies to conduct patient assessments, surveys and interventions to improve patient outcomes. Contact Joe Morse at (407) 992-8752.

◆ **CMS says it has extended the comment period for its proposed rule on a bundled prospective payment system for Medicare outpatient end-stage renal disease dialysis facilities to Dec. 16 from Nov. 16.** The proposed rule was published in the Sept. 29 *Federal Register* (*SPN 10/09, p. 1*). The audio recording of the Oct. 23 Town Hall Meeting on the rule is available through Dec. 16 as well. To access it, dial (800) 642-1687 and use ID 33239635. View the proposed rule at <http://edocket.access.gpo.gov/2009/pdf/E9-22486.pdf>.

◆ **PEOPLE ON THE MOVE:** The Apothecary Shops named **Keith Cook** president. He was previously vice president for clinical operations at Medicine Shoppe International. The company also named **Gary Williams** CFO. He was previously vice president of financial services at Avnet Technology Solutions North America... The FDA appointed **Ann Witt** counselor to the deputy commissioner for policy. She was previously counsel to Rep. Henry Waxman (D-CA)... Managed Health Care Associates, Inc. named **Pegeen Butterfield** senior vice president (SVP) of trade relations. She was previously senior director of business development at Medco... McKesson Corp. promoted **Mark Walchirk** to president of McKesson Specialty Care Solutions. He was previously SVP and chief operating officer at McKesson U.S. Pharmaceutical... OncoMed named **Ellen Scharaga** SVP of oncology pharmacy services. She was previously VP of pharmacy services at Group Health Inc... Putnam Associates promoted **Domenick Bertelli** to partner. He was previously a principal with the firm... US Oncology, Inc. appointed **Roger W. Anderson, Dr.P.H.**, chief pharmacy officer. He was previously SVP and chief pharmacist at Medco.

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