Specialty Care Management Program

Our high-touch Specialty Care Management Program provides a seamless member experience by helping to ensure appropriate medication utilization and compliance, offering targeted condition education and Disease Therapy Management, offering your members support and education for controlling side effects, and offering specialized handling and distribution of medications. Other cost-saving benefits you will see include:

**Minimal member confusion**
Members receive care coordination, fulfillment and educational needs from a single source, making it easier for them to adhere to their medication therapies.

**Optimal medication compliance**
Members receive refill reminders and delivery tracking and follow-up, and you receive enhanced reporting and outcomes management – all to help monitor medication compliance and keep costs in check.

**An integrated solution platform**
You receive extensive medical and specialty pharmacy analysis comes from us, which simplifies analysis of program performance and spend trend for you.

**Comprehensive Client Services**
We will work closely with you to design a pharmacy benefit plan that meets your needs. To achieve this, we provide:

- Benefit design consultation
- Expert specialty drug pipeline analysis
- Formulary and rebate management
- Competitive discounts

Prescription Solutions Specialty Pharmacy delivers on this promise through the integration of four core program components:
Proven Utilization Management Programs
We closely monitor your members to ensure that their use of specialty medications is safe, appropriate, and cost effective for them and for you. Specific utilization management services include:

- Prior authorization
- Step therapy
- Quantity/dose review and optimization
- Drug utilization review

Medication Delivery & Compliance Program
Our state-of-the-art Mail Service Pharmacy sends refrigerated injectable medications via express delivery to patients for self-administration at the location of their choice, or to providers for administration to patients in their offices. But we do more than just provide the medications — we also provide all the medication-related supplies a member will need. In addition, our Specialty Pharmacists help your members manage their condition and remain compliant with their medication therapy by providing support through:

- Proactive refill reminder calls.
- Answers to their questions about their drug therapy, medical condition, nutrition and financial resources.
- Suggestions about how to better monitor and manage their symptoms and side effects.

Clinical Educational Tools
Members receive mailings containing information about medications and topics specific to their medical condition, encouraging them to take a more active role in their own care. Specific conditions addressed include Hepatitis C, Hemophilia, Multiple Sclerosis, Respiratory Syncytial Virus (RSV), and Rheumatoid Arthritis. More clinical information is also available at www.PrescriptionSolutions.com.

Disease Therapy Management
Patients with certain chronic conditions — Hepatitis C, Multiple Sclerosis and Rheumatoid Arthritis — are automatically enrolled in our Disease Therapy Management (DTM) Program for enhanced compliance management. This program is designed to educate patients about their condition and improve their overall quality of life. DTM services include:

- Individualized care plan, which provides self-care tips and additional resources or educational materials. The care plan is also sent to the member’s prescribing physician.
- Case review and personalized phone consultations with our DTM clinicians, comprised of highly-trained registered nurses and pharmacists.

Extensive Specialty Pharmacy Drug List
Our Specialty Pharmacy is truly a one-stop shop with nearly 400 specialty medications available in more than 25 therapeutic categories. This includes both injectables and high-cost oral medications. In addition, we coordinate member access to “limited distribution” specialty medications.
Questioning a $30,000-a-Month Cancer Drug

A newly approved chemotherapy drug will cost about $30,000 a month, a sign that the prices of cancer medicines are continuing to rise despite growing concern about health care costs.

The price of the new drug, called Folotyn, is at least triple that of other drugs that critics have said are too expensive for the benefits they offer to patients. The colon cancer drug Erbitux, for instance, costs $10,000 a month and the drug Avastin about $8,800 when used to treat lung cancer. The price of Folotyn “seems way higher than I heard of before,” Robert L. Erwin, president of the Marti Nelson Cancer Foundation, a patient advocacy group. “I can’t imagine there not being a backlash against the pricing.”

Drug makers in general have been raising prices sharply in advance of the possible passage of health care overhaul legislation, according to various studies. But the price of cancer drugs has been an issue for several years.

Critics, including many oncologists, say that patients and the health system cannot afford to pay huge prices for drugs that, on average, provide only a few extra months of life at best.

And Folotyn has not even been shown to prolong lives — only to shrink tumors. The drug was approved by the Food and Drug Administration in late September as a treatment for peripheral T-cell lymphoma, a rare and usually aggressive blood cancer that strikes an estimated 5,600 Americans each year. It is available for sale, but its manufacturer, Allos Therapeutics, does not plan to start actively promoting it until January.

Allos defends the price, saying it made a significant investment to develop the first approved drug for this type of cancer.

“IT’s a very aggressive disease, and patients right now have no options,” said James V. Caruso, the chief commercial officer for Allos, a 17-year-old publicly traded company based in Westminster, Colo., that has no other drugs on the market.

Mr. Caruso also said the price of Folotyn was not out of line with that of other drugs for rare cancers. Patients, moreover, are likely to use the drug for only a couple of months because the tumor worsens so quickly, he said. So the total cost of using Folotyn will be less than for many other drugs with lower monthly prices.
“We believe we are fairly priced,” he added, “and we’re benchmarked” against other drugs. In a conference call with analysts last month, Mr. Caruso said Allos had “not had pushback of any type at this point” from insurers.

Some drugs for rare cancers are close to Foltyn’s price. Genzyme’s Clolar for pediatric leukemia costs about $34,000 a week, though the company says that only two weeks of treatment are typically needed. Genzyme’s drug Campath, for chronic lymphocytic leukemia, costs about $5,000 a week for several weeks.

GlaxoSmithKline is charging up to $98,000 for a six-month treatment course of Arzerra, a drug approved in late October for chronic lymphocytic leukemia, which strikes about 15,000 Americans a year. About $60,000 of the cost would be incurred in the first eight weeks, when the drug is given more frequently.

Gloucester Pharmaceuticals, which won approval in November for a drug to treat cutaneous T-cell lymphoma, another rare cancer, declined to discuss what it would charge when that treatment, called Istodax, goes on sale in January.

Despite such comparisons, Dr. Lee N. Newcomer, senior vice president for oncology at the big insurer UnitedHealthcare, called the price of Folotyn “unconscionable.” He said that Folotyn alone would cost as much as UnitedHealthcare now typically spends in total to treat a lymphoma patient from diagnosis until death. That median expenditure now, he said, is $87,000 for a little over a year of treatments.

But Dr. Newcomer said insurers would be obligated to pay for Folotyn because there were no alternatives.

Folotyn has not yet shown an effect on longevity. In the clinical trial that led to approval of the drug, 27 percent of the 109 patients experienced a reduction in tumor size. The reductions lasted a median of 9.4 months.

But considering all the patients in the trial, only 12 percent had a reduction in tumor size that lasted for more than 14 weeks. The trial did not compare Folotyn to another drug or a placebo.

“This drug is not a home run,” Dr. Brad S. Kahl, a lymphoma specialist at the University of Wisconsin, said during a meeting of an advisory committee to the F.D.A. on Sept. 2. “It’s not even a double. It’s a single.”

Saying that even a single was helpful, Dr. Kahl was part of a majority on the panel that recommended approval of the drug, 10 to 4.

But after recently learning what Allos planned to charge for Folotyn, Dr. Kahl said he was “disappointed” by the “excessive” price.

“It dampens my enthusiasm for using that drug,” he said. “It creates these huge ethical quandaries about trying a drug that has a modest benefit for the average patient at enormous expense.”

Folotyn is given by a rapid intravenous procedure once a week for six weeks out of every seven. Even to try the drug for the first seven-week cycle to see if it works would cost over $50,000. In the clinical trial, the median duration of use was 70 days, which would cost roughly $70,000 to $80,000. But some patients used the drug for many months.

In a note to clients in October, Joshua Schimmer, an analyst at Leerink Swann, estimated that a typical treatment would last 3.5 months and cost $126,000, or about $36,000 a month.
For investors, a high price is usually a good thing. Mr. Schimmer’s note was entitled “Folotyn Prices High, Reiterate Outperform.” He estimated annual sales of the drug in the United States reaching about $300 million by 2014.

Patient advocacy groups say that while they wish prices were lower, high prices might be needed to encourage companies to develop new drugs.

“It’s a two-edged sword that we have to live with and deal with,” said Louis J. DeGennaro, chief scientific officer of the Leukemia and Lymphoma Society, which has received donations from Allos and other companies. “A peripheral T-cell lymphoma patient,” he said, “at first blush will see this therapy as a very good thing.”

Allos, which is still unprofitable, has lost $350 million since its founding in 1992 and failed to win approval of a previous drug.

“Every dime that goes into the company supports Folotyn,” Mr. Caruso said.

At the time Folotyn was approved in September, stock in Allos briefly peaked above $8.50 but has slipped since then, closing up 16 cents at $6.62, or an increase of nearly 2.5 percent, on Friday.

After the approval, Allos raised $93 million in a secondary stock offering. In the prospectus for that offering, the company said that one of the risks for investors was “the relative price of Folotyn as compared to alternate treatment options.” It said there was a risk it might have to lower the price or offer discounts to successfully market Folotyn.

Like many other companies with high-priced drugs, Allos has established a program to help patients arrange insurance reimbursement. It says it will give the drug free to uninsured patients who cannot pay for it any other way.

And because a patient’s out-of-pocket co-payments alone — Medicare’s is 20 percent — could be thousands of dollars a month for Folotyn, Allos is financing a co-payment assistance program run by the National Organization for Rare Disorders, a patient advocacy group.

While this helps patients, it also helps the company sell more of its drug. If the 20 percent Medicare co-payment is made, then Medicare will pay the other 80 percent of the drug’s price — or about $24,000 a month.

**Fampridine-SR™ (4-aminopyridine) — Acorda**

Fampridine-SR is an investigational oral drug being developed to improve walking ability in people with multiple sclerosis (MS). MS is a neurological disease in which the myelin sheath covering the axons of the brain and spinal cord are damaged, leading to demyelination and scarring. When this occurs, the axons cannot effectively transmit electrical impulses. Specifically, the damaged myelin exposes channels in the membrane of the axon, which allow potassium ions to leak from the axon, dissipating the electrical current. Fampridine-SR selectively blocks these exposed potassium channels, thereby allowing the electrical signals to continue past the damaged section of the axon. In a clinical trial of 301 MS patients who were randomized to receive either adjunctive therapy with Fampridine-SR or placebo for 14 weeks, the proportion of responders (changes in walking speed of a timed 25-feet walk) were 35% and 8%, respectively ($p < 0.0001$). Acorda expects a decision from the Food and Drug Administration (FDA) for the approval of Fampridine-SR by January 22, 2010. Fampridine-SR is an orphan drug and if approved, may become the first oral drug indicated for the treatment of MS. Analysts project the estimated annual sales of Fampridine-SR to reach $300 million.

**References**


**TBD (tesamorelin) — Theratechnologies**

Theratechnologies is developing tesamorelin, a growth hormone-releasing factor analog, for the treatment of human immunodeficiency virus (HIV)-associated lipodystrophy. Currently, there are no FDA-approved treatments for HIV-associated lipodystrophy. Caused by various factors, including antiretroviral therapies and the virus itself, HIV-associated lipodystrophy is characterized by body composition changes and associated metabolic abnormalities, including elevated cholesterol/lipid levels, diabetes, hypertension and insulin resistance. HIV-associated lipodystrophy includes: excess fat accumulation, where deep abdominal fat surrounds the internal organs, and fat loss where subcutaneous fat loss typically occurs in the face, limbs and buttocks. A clinical trial involving 412 HIV patients demonstrated that after 26 weeks of treatment, tesamorelin significantly decreased visceral adipose tissue by 15.2% compared with an increase of 5% in the placebo group. Tesamorelin also significantly improved total cholesterol, triglyceride and high-density lipoprotein levels vs. placebo. Tesamorelin is administered as a subcutaneous injection. The FDA’s Endocrinologic and Metabolic Drugs Advisory Committee will review tesamorelin during the first quarter of 2010. Theratechnologies expects a decision from the FDA for the approval of tesamorelin by April 2010.

**References**

About Prescription Solutions

Prescriptions Solutions is more than just a mail order pharmacy. We are a focused, collaborative, and innovative leader in the pharmacy benefit management (PBM) industry. Today, we serve more than 10 million people through our state-of-the-art mail service pharmacies and a national network of more than 64,000 community pharmacies. We manage prescription drug benefits of commercial, Medicare, and government health plans, and those of employers and unions.

Prescription Solutions: Your Integrated Specialty Pharmacy Solution

With the sheer number of specialty pharmaceuticals and the high costs associated with them, it makes sense to address specialty pharmaceuticals with a completely integrated solution.

Yet administering an effective program requires intensive effort. The dollars are high, the patient populations are small, the administration complicated and the medications themselves require care beyond the norm. Prescription Solutions meets these challenges by applying proven pharmacy and medical management techniques - utilization management, targeted disease interventions, case management, prior authorization and health outcomes management, for example.

The result is a program that provides you with a single source for all specialty pharmacy needs. Medications are ordered, overnight delivery is coordinated, patients are monitored, claims are captured and data is tracked. In the process, you'll see a positive impact on your injectable and overall medical costs.