Managing Specialty Drugs Across the Medical and Pharmacy Benefits

Angela Maas, Managing Editor, Specialty Pharmacy News
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*Specialty Pharmacy News* is a monthly newsletter packed with 12 pages of business news and management strategies for containing costs and improving outcomes related to high-cost specialty products. Designed for health plans, specialty pharmacies, PBM, pharma companies, providers and employers, the hard-hitting newsletter contains valuable insights into benefit design tactics, specialty markets for certain conditions, formulary decisions, merger and acquisition activity, payer-provider partnerships, patient adherence strategies, and new products.

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Introduction

Although specialty drugs can be adjudicated under both the pharmacy and the medical benefit, health plans traditionally have focused on managing only those drugs that fall on the pharmacy side and have been hands off on medical-side therapies. But that approach would be a mistake, as industry estimates show that 50% or more of a plan’s specialty costs fall on the medical side.

Generally health plans place self-administered drugs in the pharmacy benefit and physician-administered therapies in the medical benefit. Most plans have various utilization tools available under the pharmacy benefit — but the medical benefit is a different story. Many plans are not even aware of what they’re spending on specialty therapies that fall on the medical side.

One tactic encouraged by PBMs is to shift specialty drugs from the medical side to the pharmacy benefit in order to easier manage them. But some payers are choosing to leave the drugs in the medical benefit and manage them there. In these pages, you’ll learn about the details of some of these strategies and some of the outcomes they’re producing.

We welcome your comments, suggestions and additional information for future editions of this report. Please send them to our book editor, Erin Trompeter, at etrompeter@aishealth.com. Thanks for your help in keeping us up to date with the rapidly changing landscape of specialty pharmacy management.

Angela Maas
Managing Editor
Specialty Pharmacy News
Site-of-Care Optimization Can Reap Big Medical Benefit Savings

Most in the specialty pharmacy industry contend that the pharmacy benefit has many more management tools at its disposal than the medical benefit does. However, site-of-care optimization is one tool available for use in only the medical benefit. And one company is demonstrating that this tactic can produce big savings when it comes to managing infusible specialty therapies that have various options for site of administration.

When all of the locations are equally safe and efficacious, shifting specialty infusions from higher-cost locations — typically the outpatient setting — to lower-cost treatment sites without any changes in the drug and its dosage can result in savings of 20% to 60% per infusion, according to a Walgreen Co. internal analysis of more than 5.3 million commercial managed care lives from January 2008 through December 2010. When you consider that infusions could cost anywhere from $500 to $20,000 per treatment, those can be significant cost savings, contends Michael Einodshofer, director of utilization management at Walgreens.

“A very few number of drugs can’t be given in an alternate site,” says Einodshofer. He adds that there is an “occasional need for the outpatient setting, such as if a patient has had a significant hypersensitive reaction to an infusion before. If they go into anaphylaxis, they are already in the hospital” and don’t have to spend valuable minutes being transported there.

Among Walgreens data, eight out of the top 10 specialty drugs infused in the outpatient setting were oncology drugs, with Tysabri (natalizumab) — approved for multiple sclerosis and Crohn’s disease — and Remicade (infliximab) — approved for various inflammatory conditions, including rheumatoid arthritis and Crohn’s — rounding out the group.

Outpatient Costs Are Usually Higher

As health plans have decreased physician reimbursement, many providers “are walking away from” infusing patients in their offices because it’s “not economically sensible,” Einodshofer says. Instead, they’re sending these patients to an outpatient location for this service. But due to various contracts with payers, “the same drug at the same dose can be a different price” at different locations. In fact, Walgreens found that costs for these therapies in outpatient hospitals were an average of 86% higher than costs at alternative sites such as the physician’s office, a patient’s home and infusion suites.

The study shows potential savings of $26 million for every 1 million patients within commercial plans when administration of the 10 drugs is moved from the outpatient facility, Einodshofer tells AIS. In addition, he says, shifting Tysabri and Remicade administration alone could save $6.3 million.

It’s important to remember that although the patient population on specialty drugs is often relatively small, the high costs of many of these drugs represent a tremendous percentage of drug spend. For example, Walgreens data for a large MCO show only five people taking the drug Soliris (eculizumab), which is approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria and patients with atypical hemolytic uremic syndrome. If those members are shifted to a less-expensive site of administration, this can produce annual savings of $78,800 per member — or $394,000 in total annual savings.

Walgreens offers three different types of infusion facilities:
(1) Stand-alone infusion centers, which are suites that exist solely for infusions;
(2) Infusion suites within Walgreens stores, which are similar to the company’s Take Care clinics; and
(3) Infusion centers within infusion pharmacies.

When Walgreens begins working with a client, among the steps it takes is performing a geographic access analysis to determine where infusion locations are in relation to where patients need treatment. Einodshofer tells AIS that “we’re more than happy” to build a Walgreens facility in an area where one is needed.

He points to a Montana employer group that is a Walgreens client. Many of the physicians in its network were sending patients to the outpatient setting for Remicade infusions. “The employer changed the benefit design to a zero copay” for Walgreens locations, a change that resulted in savings of $3 million in the first year.

Payers that wish to modify their approach to where infusions are given “typically don’t need to change their contracts,” says Einodshofer. Analyzing data — including which drugs are commonly infused, where and by whom — can show which direction to take. For instance, Walgreens had a large Blues plan client in the Northwest that had “a lot of Remicade infused at an outpatient facility,” he says. The plan was reimbursing these claims at “40% to 50% higher than what they paid for administration at an alternate treatment site.”

Walgreens was able to show that gastroenterologists referred patients to the outpatient hospital setting 70% of the time. That allowed the firm to develop an implementation plan to selectively approach the gastroenterologists to ask them to change their site of referral. Physicians referring patients to the outpatient hospital setting typically wouldn’t lose any reimbursement because they already were sending patients to the hospital. “Because of lack of knowledge about alternate treatment sites, the outpatient hospital often becomes the default choice of infusion location once a provider decides he or she does not want to provide the infusion within their own office,” he says. “Assuming that the safety, quality and convenience are there” and payers make the “process easy” for providers, this should be a relatively simple change to make.

That said, “benefit design is absolutely critical” and needs to align “with the behavior the health plan wants to encourage,” says Einodshofer. For example, if a plan has a 0% copay at an outpatient facility but a coinsurance due for infusions at alternate locations, the plan is incentivizing members to go to the outpatient location. This means that the plan will absorb 100% of those outpatient costs rather than sharing them with members.

Payers also should keep in mind that “the pipeline is an incredibly important thing to keep an eye on,” as more infused specialty therapies are coming down the pike. And “while only a handful — maybe 20 or so — of specialty infusions are material, 10 of those really drive the majority of spend…. This is an issue today, but will be an even bigger issue tomorrow.”
Ensuring Appropriate Drug Use and Site of Service Could Be Improved

Health plans definitely have made strides in their management of drugs under the medical benefit. However, opportunities still exist to provide more efficient and effective care, according to data in ICORE Healthcare’s second edition of the Medical Pharmacy & Oncology Trend Report.

One section of the report is based on responses from commercial health plan medical directors and pharmacy directors of 60 health plans managing more than 153.2 million lives, up from the 146.3 million managed in the 2010 report. The survey was conducted in June and July 2011 and includes information on current and future benefit trends.

The second section of the report is based on data from paid medical and pharmacy claims for full-year 2009 and 2010 based on a proprietary data set from multiple regional and national health plans. The claims were across all lines of business, sites of service, and medical and pharmacy benefits.

ICORE President Michael Waterbury tells AIS that one interesting finding in the report is the continuing trend of hospital-based administration of specialty drugs and treatment of conditions such as cancer and rheumatoid arthritis. “Community oncologists are going out of business and selling their practices to hospitals because the margins aren’t where they need them to be,” he explains.

Physician offices represented almost half of the medical injectable billed claims in 2011 (45%, up from 44% in 2010), but the outpatient and inpatient settings in total weren’t far behind. The percentage of medical injectable claims from the hospital outpatient setting dropped slightly from last year’s report, from 27% to 25%, but inpatient claims rose from 10% to 12%. The home health setting saw a decrease as well, from 18% to 15%.

Patients, Waterbury contends, will receive better care when they are continually evaluated by the same physician. But when those patients are receiving drugs through the outpatient setting, “that continuity is fragmented, and there is not an improvement in the quality of care.” And with patients with compromised immune systems being exposed to nosocomial infections in the hospital setting, those people “may walk in, but they may not walk out.”

Health plans “should focus on driving cost and quality of care.” Community oncologists “spend a fair amount of time” with patients and represent “the highest quality and the lowest cost” of care, he says.

### Off-Label Utilization for the Top 25 Drugs (2010)

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>All Lines of Business</th>
<th>Commercial</th>
<th>Medicare</th>
<th>Medicaid</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Allowed Per 1 Million Lives (% of Total)</td>
<td>All Claims Per 1 Million Lives (% of Total)</td>
<td>All Allowed Per 1 Million Lives (% of Total)</td>
<td>All Claims Per 1 Million Lives (% of Total)</td>
</tr>
<tr>
<td>On-Label</td>
<td>$137,075,407 (93%)</td>
<td>62,786 (95%)</td>
<td>$138,176,959 (93%)</td>
<td>62,468 (94%)</td>
</tr>
<tr>
<td>Off-Label</td>
<td>$10,656,434 (7%)</td>
<td>3,586 (5%)</td>
<td>$11,118,355 (7%)</td>
<td>3,646 (6%)</td>
</tr>
</tbody>
</table>

**SOURCE/METHODOLOGY:** ICORE Healthcare, Medical Pharmacy & Oncology Trend Report, second edition, released Dec. 2011. Data are from paid medical and pharmacy claims for full year 2010 based on a proprietary data set from multiple regional and national health plans. Claims were across all lines of business, sites of service, and medical and pharmacy benefits.
The survey notes that the majority of plan members were with payers that have put in place programs to try to curtail shifts in the site of service to hospitals, “although the success of these programs is generally not known.”

The report shows that overall medical and pharmacy spend among oncology and certain therapeutic injectable classes in 2010 was almost $270 million per million lives — “almost one-quarter of $1 billion,” notes Kjel Johnson, Ph.D., senior vice president with Magellan Pharmacy Solutions (see table, below), an operating unit of Magellan Health Services, Inc., which purchased ICORE in 2006. Still, the year-over-year trend was flat, due to (1) a couple of top drugs, including Taxotere (docetaxel) and Eloxatin (oxaliplatin) — No. 7 and No. 10 among the highest-cost medical benefit injectables/infusibles, respectively — facing generic competition, and (2) effective plan management of these costs, he says.

A medical claims analysis compared the classified and unclassified codes — including so-called “dump” codes such as J3490 — paid by commercial payers. For 2010, more than $227 million in classified codes were allowed per 1 million lives, while only $882,851 in unclassified codes were paid, representing 0.4% of medical benefit claims analyzed.

Johnson points out that there are “whole initiatives focused on [determining what nonspecific codes are for], but it is a miniscule spend.”

Still, says Waterbury, “I’m shocked at how many high-cost nonspecific diagnosis codes are used,” including codes for $8,000 and $10,000. “It’s amazing how low the bar is,” he says. And while some of the codes may be for drugs just approved that don’t yet have a Healthcare Common Procedure Coding System (HCPCS) code, Waterbury wonders if some of the other use is “intentional [nonspecific coding] because people don’t want to be managed.”

He maintains that “it’s so much work to make sure drugs are used appropriately and paid appropriately.” Prior authorization is one tool that can help in this area, as is “bridging the communication gap” between payers and providers.

### Spend by Key Therapeutic Class (Medical and Pharmacy)

<table>
<thead>
<tr>
<th>Therapy</th>
<th>2009</th>
<th>2010</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV chemotherapy</td>
<td>$89,181,960</td>
<td>$81,881,838</td>
<td>33%</td>
<td>31%</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>$32,666,943</td>
<td>$35,510,361</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>Granulocyte colony-stimulating factor</td>
<td>$20,472,358</td>
<td>$20,652,866</td>
<td>8%</td>
<td>8%</td>
</tr>
<tr>
<td>Oral chemotherapy</td>
<td>$17,911,263</td>
<td>$18,181,125</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Intravenous immune globulin</td>
<td>$15,090,615</td>
<td>$16,088,787</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Chemotherapy support – unspecified</td>
<td>$10,185,650</td>
<td>$10,207,388</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>$9,396,503</td>
<td>$8,477,727</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Erythropoiesis-stimulating agent</td>
<td>$9,611,659</td>
<td>$8,227,824</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Antiepileptics</td>
<td>$5,545,859</td>
<td>$4,846,520</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>$57,434,542</td>
<td>$63,147,583</td>
<td>21%</td>
<td>24%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$267,497,351</strong></td>
<td><strong>$267,222,020</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

SOURCE/METHODOLOGY: ICORE Healthcare, Medical Pharmacy & Oncology Trend Report, second edition, released Dec. 2011. Data are from paid medical and pharmacy claims for full year 2009 and 2010 based on a proprietary data set from multiple regional and national health plans. Claims were across all lines of business, sites of service, and medical and pharmacy benefits.
Off-label use for the top 25 medical injectables compared with use consistent with FDA approval and inclusion in National Comprehensive Cancer Network guidelines was fairly similar across all lines of business, representing about 7% of the total spend per 1 million lives across commercial, Medicare and Medicaid plans (see table, p. 3).

“There are still a substantial amount of drugs used for what they shouldn’t be,” Waterbury says. For example, the report took a close look at paid claims for Aloxi (palonosetron HCl), Kytril (granisetron HCl) and Zofran (ondansetron HCl), drugs used to treat chemotherapy-induced nausea and vomiting, to see what type of regimens they were used with. Aloxi is indicated for use with moderately and highly emetogenic chemotherapies, but claims showed that 37% of its use was with low emetogenic chemotherapies. “There’s not one clinic in this country or manufacturer that would say that’s appropriate use,” he contends.

And although payers and providers have not necessarily been on the same page with health care services over the years, that divide seems to be getting smaller. “Oncologists are realizing that it’s an unsustainable model to do anything, anywhere, using any drug they want,” says Johnson. There “is some effort” on their part; they “want to be reasonable.”

But that effort needs to come from both sides, he says, noting that for health plans, “it’s not reasonable to prior auth all [specialty] drugs, but it’s reasonable to prior auth the top 10 drugs.”

According to Waterbury, “Everyone is looking to ACOs [i.e., accountable care organizations]...and the government to see if they can create a model that works.” He asserts that “Physicians have had a long history of not executing on ideas.” And while “physicians are strong clinically and in interacting with patients” and coming up with good ideas, the follow-through effort, as well as determining how to measure and report outcomes and handle contracts, often has left a little to be desired.

**Coinsurance Rise May Seem Small, but...**

Almost half of plan respondents (43%, up from 41% in the previous report) say they require neither coinsurance nor a copay for medical injectables. The number requiring only coinsurance rose from 21% in the last report to 27%, while copay-only plans rose from 18% to 20%. The percentage of plans that require both coinsurance and a copay, though, dropped from 20% to 10%.

In the first edition of the report, all plans reported they require an average 17% coinsurance, which rose to 20% in the latest edition. Respondents say they expect that percentage will rise to 22% in 2012. And while these may seem like only slight increases, Johnson points out that some injectable/infusible drugs may have annual price tags of $80,000 — which means a 2% coinsurance increase is another $1,600 for which members will be responsible.

The pharmacy benefit traditionally has been easier than the medical benefit when it comes to payer implementation of management strategies. However, the report shows that health plans with about 65% of the total lives represented in the survey have some formulary management of injectables/infusibles on the medical side. That percentage is actually down from 75% in the prior report, a fact that Waterbury says is “surprising to me....I wasn’t necessarily expecting to see a decrease.”
This could be due to the fact that when a sophisticated health care person hears the term “formulary,” he or she probably thinks of tiers, copayments and pharmacy cards, he says. Waterbury, however, says that more plans are “saying they are putting in more controls on the medical side”—although not necessarily a formulary—to try to emulate the management tactics on the pharmacy side. “I do believe plans have been working hard” on this, he says. �有自己的话
Managing Specialty Pharmacy Medications Accessed Through the Medical Benefit: Challenges and Strategies

Beckie Fenrick, Pharm D, MBA
Senior Director, Pharmacy
AIS Webinar - November 3, 2011

Objectives

- Understanding Measuring utilization and cost trends for medications accessed in physicians’ offices, home infusion providers, facilities and specialty pharmacies
- Consider member engagement strategies to assure optimal pharmaceutical care for complex drug regimens
- Provider engagement to optimize cost effective care
- Address appropriate use through utilization management and other strategies
You can’t manage what you don’t measure

Utilization and spend trends for medications on the medical benefit

Where to begin? What do you measure?

• Hospital Outpatient
• Hospital Inpatient
• DME
• Home Infusion
• Ambulatory Infusion Suites
• Skilled Nursing Facilities
• Specialty Pharmacies
• Physician Office
Measurement Challenges pharmacy benefit and health benefit

**What’s happening with PBM adjudicated claims?**
- Pre-strategy implementation trend 25%
- Post-strategy implementation trend 8%

**What’s happening on the health benefit (professional medical claims)?**
- Trends as high as 25%
- Oncology a key focus

**What’s happening with facilities, infusion suites, and home infusion**
- Trends showed areas of concern
- Address appropriate use and cost

Benefit Designs Working Into The Future

A key consideration for medication coverage is appropriate member cost share on both the pharmacy and medical benefit.

Access to medications and other service

Appropriate use and appropriate location of service

Affordability through high quality networks and high quality medical services
Care Management
High Touch Care Model integrated with Pharmacy and designed to deliver better Health Outcomes for Members

WELLNESS COACHING
- Worksite Wellness
- Lifestyle Coaching
- Behavioral Risk Screening

24 X 7 NURSE ADVISE
- Symptom Support
- Behavioral Health Coaching
- Decision Support

NAVIGATION AND CONSULTING
- Benefit Optimization
- Care Referrals
- Social and Community Resources

CONDITION MANAGEMENT
- Core Chronic
- Rare Chronic
- Complex
- Oncology
- Transplants
- Prenatal Program

CARE COORDINATION
- Facility Admissions (pre/post and concurrent review)
- Care Management
- Discharge Planning
- Call After Discharge

Examples
Rheumatoid Arthritis
Psoriasis
Oncology
Osteoarthritis
Osteoporosis
IVIG
Gout
Substance Abuse
Managing Therapeutic Classes Across Channels and Benefits

Facilities
- Inpatient and Outpatient
- Physician Office
- Home Infusion and Ambulatory Infusion Suites
- Traditional Pharmacy Benefit Channels

Channels To Access Medications

Pharmacy Providers
- Retail
- Specialty Pharmacy
- Mail Order Pharmacy

Facility and Ancillary Providers
- Home Infusion
- Ambulatory Infusion Suites
- Inpatient Facility
- Outpatient Facility

Physician Providers
- Buy and Bill
- Drug Replacement
Blue Cross and Blue Shield of Florida is an Independent Licensee of the Blue Cross and Blue Shield Association.

BCBSFL Provider Administered Drug Program

- Rational Fee Schedule
- Pre-Service Review
- Post Service Pre-payment edits

Oncology Management Considerations

- Managing Cost and Utilization Across Multiple Channels
- Physician Office Fee Schedule Assessment
- Pathways
- Molecular Genetics
- Care Management, Case Management and Utilization Management
- End of Life Care
Oncology Examples

Prostate Cancer—sipuleucel-T, cabazitaxel, and abiraterone acetate enter the market

- Benefit Design: sipuleucel-T and cabazitaxel health benefit; abiraterone acetate drug benefit
- New Product and New Indication Evaluation Process: sipuleucel-T, cabazitaxel and abiraterone acetate unique considerations
- Through which channels is the medication available for our members—sipuleucel-T primarily accessed through provider office; cabazitaxel provider office or facility; abiraterone acetate accessed through retail or specialty pharmacy
- Appropriate use—safety concerns and biomarkers
- Measure Utilization and Cost Trend
Melanoma—ipilimumab and vemurafenib enter the market

Benefit Design—ipilimumab health benefit; vemurafenib drug benefit

New Product and New Indication Evaluation Process—ipilimumab and vemurafenib unique considerations

Through which channels is the medication available for our members—ipilimumab primarily accessed through provider office or facility; vemurafenib accessed through retail or specialty pharmacy

Appropriate use—safety concerns and biomarkers

Measure Utilization and Cost Trend

Integrating Pharmacy and Medical Benefits

Lynn M. Nishida, R.Ph.
Director
RegenceRx

AIS Webinar – November 3, 2011
Traditional Prescription/Medical Benefits

Prescription Benefit

- Diabetes
- Antidepressants
- Hypertension
- Hyperlipidemia
- PPIs
- Glaucoma

Medical Benefit

- Oncology
- Rheumatology
- Psoriasis
- Contraceptives
- Chronic ITP
- Multiple Sclerosis
- Osteoarthritis
- Growth Hormone
- Asthma
- Antiemetics
- Vaccines
- PAH
- ESAs
- CAPS

Diagnoses:
- CAPS = Cryopyrin-Associated Periodic Syndromes

Biologics for Inflammatory Conditions—Considerations

<table>
<thead>
<tr>
<th>Generic [brand] (FDA approval)</th>
<th>Administration Frequency</th>
<th>Physician Office</th>
<th>Risks with Dose Increases</th>
<th>Differentiating Safety Considerations</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>infliximab [Remicade] (8/1998)</td>
<td>Every 4 to 8 weeks X X</td>
<td>12 year record</td>
<td>$12 K – 78 K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>certolizumab pegol [Cimzia] (4/2008)</td>
<td>Every 2-4 weeks</td>
<td>2 year record</td>
<td>$22 K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>golimumab [Simponi] (4/2009)</td>
<td>Every 4 weeks</td>
<td>1 + year</td>
<td>$22 K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rituximab [Rituxan] (11/1997)</td>
<td>2 doses then stop X</td>
<td>12 year record</td>
<td>$13 K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>tocilizumab [Actemra] (1/2010)</td>
<td>Every 4 weeks X X</td>
<td>WBC, ANC, LFT, cholesterol with each infusion; limited to use if TNF failed</td>
<td>$17 K – 33 K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>alefacept [Amevive] (1/2003)</td>
<td>Every 12 weeks X</td>
<td>7 year record Monitor CD4 counts</td>
<td>$13 K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>natalizumab [Tyysabri] (11/2004)</td>
<td>Every 4 weeks X</td>
<td>Life-ending progressive multifocal leukoencephalopathy (PML)</td>
<td>$37 K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>abatacept [Orencia] (12/2005)</td>
<td>Every 4 weeks X</td>
<td>4 year record</td>
<td>$24 K</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 - Potential risk of serious adverse effects with dose increases
2 - Approximate annual cost based on AWP, assumes 80 kg patient
3 - Cost for 2 infusions
4 - SQ: Subcutaneous Injection
Need for Medication Integration

- 40 y/o male with ankylosing spondylitis
- Remicade x 5 months
  - Required prednisone 5 mg daily
  - Morning stiffness x 2 hours
  - Pain 7/10
- Prescription for Humira
- Prior auth request for Remicade

High Cost Medication Options
Span Prescription and Medical Benefits

Examples: Rheumatoid Arthritis, Oncology
Many Options - Oral, SubQ, IV

Traditional
Rx = Member pays 50%
Medical = Member pays $0, after MOOP met in 1-2 months
- Member chooses lowest out of pocket
- Unnecessary overall costs incurred

New Landscape
Rx = $100 copay
Medical = $100 copay
Member chooses medication with the best effectiveness, safety, and value.
Assessing Value of New Medications

1 - Evaluate Evidence (greatest weight)
2 - Evaluate Other Considerations

3 - Synthesize

4 - Value Assessment
## Evaluation of Evidence

<table>
<thead>
<tr>
<th>Appraisal:</th>
<th>Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Confidence</td>
<td>Precisely estimates:</td>
</tr>
<tr>
<td></td>
<td>• Extent of benefit</td>
</tr>
<tr>
<td></td>
<td>• Chances of success</td>
</tr>
<tr>
<td>Uncertain Confidence</td>
<td>Uncertain estimations of efficacy:</td>
</tr>
<tr>
<td></td>
<td>• Bias / confounders / missing information</td>
</tr>
<tr>
<td></td>
<td>• Impact estimate of treatment effect.</td>
</tr>
<tr>
<td>Not High Confidence</td>
<td>Efficacy unknown</td>
</tr>
<tr>
<td></td>
<td>• Extent of benefit and chances of success are</td>
</tr>
<tr>
<td></td>
<td>• Unknown</td>
</tr>
<tr>
<td></td>
<td>• Bias / confounders very likely interfere with</td>
</tr>
<tr>
<td></td>
<td>• Results.</td>
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</tbody>
</table>

## Other Considerations (Most Common)

<table>
<thead>
<tr>
<th>Considerations</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Treatment Options</td>
<td>Established Treatment Options</td>
</tr>
<tr>
<td>Safety</td>
<td>Proven safety advantages</td>
</tr>
<tr>
<td>(Less Risk)</td>
<td>Established track record. Known adverse effects.</td>
</tr>
<tr>
<td>(Greater Risk)</td>
<td>Generally minor.</td>
</tr>
<tr>
<td></td>
<td>Unknown / unconvincing safety risk.</td>
</tr>
<tr>
<td></td>
<td>Or concerns are serious, but manageable</td>
</tr>
<tr>
<td>Cost</td>
<td>Total Overall Cost (all discounts / rebates)</td>
</tr>
</tbody>
</table>
Evidence-Based Value Assessment (Integrated Benefits)

- Formulary
- Medical policy
- Utilization Management
- Navigation and Advice

Integrated Pharmacy and Medical Benefits (Sample Design)

<table>
<thead>
<tr>
<th>Tier</th>
<th>Basic</th>
<th>Expanded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Self-administered</td>
<td>Non-self administered (injectables)</td>
</tr>
<tr>
<td></td>
<td>Medications &lt; $600</td>
<td>Medications &gt; $600</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specialty medications/oncology (all routes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Combined deductible and maximum out of pocket</th>
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</thead>
<tbody>
<tr>
<td>Generic</td>
<td>$5</td>
</tr>
<tr>
<td>Formulary</td>
<td>$25</td>
</tr>
<tr>
<td>Non-Formulary</td>
<td>$50</td>
</tr>
</tbody>
</table>
Building an Integrated Formulary

• Identify top opportunities (cost, options)

• Expand evidence-based review
  − Pipeline
  − Scoping (therapy class vs. condition)
  − Committees: P & T, Oncology Subcommittee
  − Full review of all medications deemed non-formulary

• Synchronize formulary status across benefits

• 25 - 30% increase in reviews

Top Opportunities
Medication Classes

<table>
<thead>
<tr>
<th>By Condition</th>
<th>Allowed (estimate) amount per year per 1 million members ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology</td>
<td>$38 Million</td>
</tr>
<tr>
<td>Arthritis/psoriasis</td>
<td>$22 Million</td>
</tr>
<tr>
<td>Asthma</td>
<td>$18 Million</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>$13 Million</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>$3 Million</td>
</tr>
<tr>
<td>Immune globulin</td>
<td>$2 Million</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>$2 Million</td>
</tr>
<tr>
<td>Pulmonary Arterial Hypertension</td>
<td>$1 Million</td>
</tr>
</tbody>
</table>

Integrated Medication Policy and Utilization Management

- Application of evidence-based value assessments
- Coverage policies and programs can be based on all available treatment options
- Unified philosophy in utilization management

Implementation Considerations

- System development
- Expanding number of medications reviewed
- It’s new – new takes time
Medication Cost Integration Benefit (Regence)

- Model
- Evidence-based foundation
- Even playing field across medications (medical and pharmacy benefits)
- Prescribers/members choose based on value
- Alternative to legislated benefits (example: chemotherapy)

Next Steps

- Apply to provider reimbursement
- Evaluate condition-specific approach for:
  - Medication options
  - Diagnostic tests
  - Devices
  - Procedures
Survey Shows Employers Need To Boost Specialty Knowledge

While specialty drugs and their high costs continue to be a rising concern among employers, many of them do not know what their spend on these therapies is. With expenses for this group of products estimated to represent a large proportion of health benefits’ costs in the next few years, employers need to have a better understanding of these therapies in order to effectively manage them.

One-quarter of respondents to a July 2011 survey of about 120 employers by the Midwest Business Group on Health (MBGH) said they have “little to no understanding” of biologics and specialty pharmacy, while 53% claimed a “moderate understanding.” Almost 70% of the respondents are self-insured companies, with 19% fully insured.

In addition, when the companies were asked about their specialty spend in the medical benefit, 70% said they didn’t know what it was; 40% didn’t know what they were spending on these products under the pharmacy benefit (see charts, p. 24). And almost 30% didn’t know how much their specialty claim costs on the pharmacy side had increased over the past three to five years.

The survey was conducted as part of a two-phase initiative by MBGH, which will develop an employer toolkit based on the results and also pilot educational programs in Chicago and Baltimore this year. In 2012, MBGH hopes to expand these efforts and conduct an additional survey, says F. Randy Vogenberg, Ph.D., a principal with the Institute for Integrated Healthcare and strategic pharmacy advisor to the Business Group Pharmacy Collaborative who is working with MBGH.

As they developed the initiative, Vogenberg says, they were certainly aware of other reports citing knowledge gaps among employers with respect to specialty pharmacy. However, those reports “had not specified what they [i.e., the gaps] were nor provided details relating it back to specific benefits. Our goal was to better determine the areas lacking awareness or knowledge as well as to quantify the 'gaps' from the employer perspective, which has not been done before in this way. Clearly these results indicate very significant knowledge gaps by employer plan sponsors who are the buyers of health care services. By quantifying those gaps in a variety of benefit coverage areas, we have created a solid baseline for measuring future performance towards improving benefits communication, design or innovation.”

With respect to the lack of knowledge as far as specialty spend, “What you don’t know can hurt more than what you do know,” contends Vogenberg. “As this area of medications continues to rapidly grow and expand, most employer plan sponsors and their benefit advisors remain ill-equipped to understand the magnitude or deal with the new technology issues now facing them in medication coverage.”

Vogenberg tells AIS that there are some takeaways from the survey for employers:

✦ A dearth of benefit innovation and medication adherence strategies shows a “lack of integrated plan design and outdated benefit management concepts that may benefit vendors but not plan sponsors or patients.”

✦ The use of traditional benefit designs and management tactics and failure to integrate specialty drugs into benefits demonstrate a “fundamental flaw” in employers’ “ability to fully
address the health delivery marketplace use of all patient care technologies — drug, device and diagnostic — along with underwriting the financial risk appropriately."

◆ The ability to help employer plan sponsors with their benefits and provide “unbiased information around biologics and specialty pharmacy is a hot-button issue today.”

According to Vogenberg, “Increasing growth in cost, as well as use, of biologics and specialty medications represents the proverbial tip of the iceberg in health care benefits.” Although many employers are focused on complying with various health reform requirements and trying to reduce pharmacy costs through the use of generics and mail-order distribution, “the real driver of cost trend growth lies in biologics and specialty pharmacy. More importantly, the timing of market events by 2015 will find the end of savings from the patent cliff at the same time that biologics and specialty pharmacy can represent more than a third of all health benefits medication spending for employer plan sponsors.” He adds that “Since the majority of employer plan sponsors from the survey results doesn’t know their costs or clearly understand biologics and specialty pharmacy, a real sense of urgency to address this area of benefits coverage is being felt by thought leaders before the market tidal wave overcomes them in a few short years.” ◆

### Biologics/Specialty Drugs Paid Through Medical Plans, Pharmacy Benefits

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>If your biologics/specialty medications are paid through your medical plan, what percentage are for biologic/specialty pharmacy products? (choose one)</td>
<td>If your biologics/specialty medications are paid through your pharmacy benefits, what percentage are for biologic/specialty pharmacy products? (choose one)</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>Don’t Know</td>
</tr>
<tr>
<td>&lt;1%</td>
<td>&lt;3%</td>
</tr>
<tr>
<td>1-2%</td>
<td>16-20%</td>
</tr>
<tr>
<td>&gt;7%</td>
<td>11-15%</td>
</tr>
<tr>
<td>3-5%</td>
<td>7-10%</td>
</tr>
<tr>
<td>5-7%</td>
<td>&gt;20%</td>
</tr>
<tr>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>20%</td>
<td>10%</td>
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<tr>
<td>40%</td>
<td>30%</td>
</tr>
<tr>
<td>80%</td>
<td>40%</td>
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</tbody>
</table>

**Plans Boost Specialty Management, but Improvement Is Still Needed**

Health plans are becoming more active in tracking and managing specialty drugs, reveals the most recent edition of the *EMD Serono Specialty Digest*. But it also shows that there are still some areas in which their management of these drugs could improve.

The 2011 report, which is the seventh edition, included three new topics: measurement and value of health outcomes, oncology molecular diagnostics management, and management across the pharmacy and medical benefits. Responses were gathered in January 2011 from 93 health plans with more than 115 million covered lives.

Asked to identify the most important outcomes measures used to determine formulary positioning for hepatitis C, multiple sclerosis, rheumatoid arthritis and oncology, respondents had “pretty consistent” feedback across the conditions, says Debbie Stern, vice president at managed care consulting firm Rxperts, Inc. and author of the report. Decreasing disease progression and severity, following health plan guidelines, and reducing hospitalizations and other health care costs were among the top responses. “But the ability to track and measure these outcomes is actually low,” she points out. “Plans say it is important, but the ability to track and measure them is not high.”

**Plans Are Not Tracking Outcomes Themselves**

So who’s responsible for tracking these data? “In a lot of senses, plans are relying on manufacturers to look at certain elements,” but they’re also depending upon independent academic research for the information, she says. And they look to specialty pharmacies for compliance and adherence data. “What plans expect to do in-house is pretty minor,” perhaps simply because they don’t have the resources available.

When it comes to management strategies for oncology molecular diagnostics, half of the respondents said they are determining whether a test is cost-effective before they cover it, and another 32% say they plan to implement this tactic within the next one to two years. Forty percent require testing before approving certain agents, and 40% also require prior authorization for the tests.

However, Stern notes that only 32% of plan respondents restrict the use of drugs based on the results of those tests. Plans “are taking all the steps except the closure,” she says. “They’re still letting oncologists make the final decision.”

Implementing such restrictions, though, “is practicing medicine in a sense,” says Stern. Data supporting that decision “need to be pretty definitive to deny” approval for a drug. “The literature has to show the test is 100% accurate.” Also important is getting consensus from community oncologists. But only 25% of respondents say they work with community oncologists to develop clinical pathways.

Another interesting finding, Stern says, was in the area of specialty pharmacy providers’ therapy management programs — “plans say they don’t really use these.” Respondents cited hepatitis C therapy management programs as the most commonly used, with 27% saying they use these. The other programs that ranked lower were ones for respiratory syncytial
virus (25%), multiple sclerosis (22%), growth hormone disorders (19%), rheumatoid arthritis/Crohn’s disease (17%), hemophilia (14%), infertility (6%) and oncology (6%).

“But from a specialty pharmacy perspective, everyone is using these therapy management programs,” she explains. “There is some kind of disconnect” between plans and specialty pharmacies.

Another new topic in this year’s digest is strategies for managing specialty drugs across the pharmacy and medical benefits. More than three-quarters — 76% — of respondents say they have clinical criteria that cover a therapeutic category across both benefits. And 72% say their pharmacy department manages specialty prior authorization across both benefits.

However, only 17% of respondents have an equal cost share for specialty drugs across the pharmacy and medical benefits. So a member who is getting a drug adjudicated on the pharmacy side could have a $75 copay, but another member with a drug that falls on the medical side could have coinsurance of 20%. The specifics “depend on the benefit design,” Stern explains. “But it really skews the selection of the drug.” This imbalance has spurred state legislation, both pending and implemented, that prohibits charging more for an oral drug than for one that is injected or infused.

Stern points to data in the digest on cost share in the medical benefit. In 2008, 70% of 57 commercial plan respondents said they did not have a cost share for drugs covered under the medical benefit. That percentage dropped to 63% (out of 64 respondents) in 2009 and 47% (out of 75 respondents) in 2010. Medicare Advantage prescription drug plans showed a similar trend, with 64% citing no cost share in 2008, then 48% in 2009 and 40% in 2010.

When it comes to coverage of office-administered agents, “we’re still not seeing OAAs being pushed over to the pharmacy benefit,” notes Stern. “We hear out on the street that PBMs that own specialty pharmacies are pushing this, but it’s not happening.” In 2008, 1% of OAAs were covered under the pharmacy benefit, a percentage that rose to 2% in 2009 and 6% in 2010.

Very small percentages of respondents have created a specialty benefit that is separate from the pharmacy and medical benefits. However, says Stern, “my crystal ball says five years from now we’ll see more of this.” Implementation shouldn’t be too onerous, she explains, and would involve rewriting the description of benefits and repricing of premiums. These drugs could still be “adjudicated through the pharmacy benefit but accrued through the specialty benefit.”

In 2008, 65% of plan respondents said they tracked their specialty drug costs and trend in the pharmacy benefit, and 29% said they tracked these in the medical benefit. In 2009, those numbers had risen to 80% for the pharmacy benefit and 64% for the medical benefit. In the most recent survey, 98% of respondents say they track specialty costs and trend in the pharmacy benefit, with 75% tracking them in the medical benefit.

“This is a huge increase,” contends Stern. “Seventy-five percent versus 29% shows this is a very significant issue, and plans are paying attention to this.”
CVS Caremark Says It Will Manage Medical Benefit, Joins Other PBMs With Service

CVS Caremark Corp. says it will begin managing drugs under the medical benefit in 2012, making it the latest PBM to offer such a service.

Specialty drugs have long posed a problem when it comes to adjudicating claims. While some of them fall under the pharmacy benefit, many more — estimates put the percentage at more than 50% of all specialty drugs — fall on the medical side. Plans have struggled to determine how best to structure their benefits in order to manage these products and to get a complete picture of members and their drug utilization.

According to CVS Caremark, “the offering is the first of its kind to provide a comprehensive management solution for the buy-and-bill drug model currently used by physicians....The payer-centric offering will employ both prospective and retrospective drug utilization management strategies to drugs billed under the medical benefit, while ensuring minimal disruption to the physician’s workflow and facilitating the delivery of evidence-based care.”

The service “is a management solution which does not include drug distribution,” says a CVS Caremark spokesperson.

The PBM will launch “several pilot programs in 2011,” with the new service offered to all customers on Jan. 1, 2012, says the spokesperson, who declines to give additional information on the pilots. Initially, the offering will focus on only oncology drugs and oncolytic supportive care therapies. “We expect to expand to other conditions, but the specific conditions and timing of those initiatives are not finalized,” he tells AIS.

In its press release unveiling the offering, CVS Caremark says it expects “estimated savings of up to 15 percent of a payer’s oncology spend.” That percentage, says the spokesperson, is based “on the client’s specific oncology drug spend that is covered under the medical benefit and administered in the physician’s office.”

Care Continuum, a subsidiary of Express Scripts, Inc., another PBM that offers medical benefit management, saved one of its clients $46 million in specialty drug costs over seven years, according to spokesperson Thom Gross.

In addition, CareFirst BlueCross BlueShield, which entered into a deal in 2008 with P4 Healthcare LLC for the vendor to apply its clinical pathways program to managing oncology for the plan, reaped savings of $8.5 million in drug costs, which is 8% of total oncology costs, in the first year of implementation. The program initially focused on breast, lung and colon cancers and supportive care for all cancers.

Tactics Can Help Control Spend

“Oncology is the biggest and most obvious category of medications to go after in the medical spend and allows for easy savings opportunities,” maintains F. Randy Vogenberg, Ph.D., a principal with the Institute for Integrated Healthcare and strategic pharmacy advisor to the Business Group Pharmacy Collaborative. He adds that “most health plans and PBMs” have some management in this area already.

“There are some very reasonable tools that can help control spend, especially in oncology,” says Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC. “Increased use
of generics, use of preferred products, and following guidelines and pathways will wring out inappropriate utilization. If you can’t get 15% out of just those three tactics, then something is wrong.”

“If it works, and oncologists and patients go along with the program, and if quality of care is monitored and is maintained, the benefit is savings, which could be in dollars saved or reduced drug trend over time,” explains Elan Rubinstein, Pharm.D., founder and principal of consulting firm EB Rubinstein Associates. “Per the press release, it appears that Caremark/New Century are not ready to address cost savings beyond giving a flat percentage estimate and saying that there are associated program fees, but not saying what the net of claims cost less program fees might be, nor offering a guarantee of return on investment.”

The CVS Caremark spokesperson confirms that “there will be a fee” for this offering that “will depend on the scope of services provided to our customers.” Vogenberg notes that “this is typical of any benefit management service offering by a PBM.”

The PBM is partnering with New Century Health, a company that was created through the May 2010 merger of New Century Infusion Solutions, an integrated single-specialty provider in oncology, and New Century Health Management Systems, Inc., a third-party administrator. Both companies were founded by Joseph Perez, who serves as president of New Century Health.

According to that company’s website, it integrates “evidence based medicine, treatment care pathways, quality improvement programs, and peer-to-peer review using our web-based technology platform to reduce variations in care and to drive cost savings for our clients. These services are provided across all lines of business (Medicare, Medicaid, and Commercial), including both medical and pharmacy data.”

“New Century Health is a strong partner to complement our offering,” says the CVS Caremark spokesperson. “They bring an outstanding technology platform that is being used in the market today. In addition, they have tremendous experience working with national and regional payers and with community-based oncologists and hematologists.”

A New Century spokesperson declines to elaborate on the platform and experience the company provides.

**PBM May Need to Overcome Hurdles**

The past few years have seen a few PBMs testing the medical benefit management waters. But as PBMs enter into managing drugs that are adjudicated under the medical benefit, there are some hurdles they may need to overcome along the way.

For example, Rubinstein wonders whether “major insurance companies [will] allow New Century as part of Caremark to manage their oncology care.” And, perhaps more importantly to the broader market, “do insurers think a PBM is up to the task, that this is a core competency?”

Still, says Sullivan, the tactics used to manage the medical benefit “aren’t unique to a PBM; instead, these tactics are simply proactive and targeted interventions that are based on current best practices and, in fact, can help to reduce prior authorizations, not increase them a la the PBM model.”
Perhaps the biggest benefit to clients, he points out, is a single point of contact. If CVS Caremark “can integrate medical and pharmacy reporting and actually produce total cost of care analyses and predictive modeling, then there would be very tangible benefit. That, however, is a BIG ‘if.’”

According to Rubinstein, “unless insurers implementing the Caremark/New Century program are willing to adjust oncologist compensation or contracts to incentivize cooperation with these new care standards, and also change benefit designs to encourage cooperation with the value of evidence-based preferred therapies, it is likely that both oncologists and patients will resist, or just not cooperate.”

Were noncooperation to occur, “and the insurer has neither changed oncologist payment/contract nor benefit design, will Caremark/New Century (1) deny coverage in a prior-authorization situation, or (2) recommend to deny coverage and refer to the insurers’ medical director for a final decision?” he asks. “In a post-claims review, will Caremark/New Century have these same options? If coverage is denied, will there be sufficient depth in the process and method to withstand challenge? Clearly insurers are ready to address oncology, but I’m concerned with whether these pieces will fit together well.”

The spokesperson responds that “the CVS Caremark program is based upon consultation and collaboration with both the payer and provider (oncologist). A robust provider engagement plan will be a key element.” The pilot programs conducted this year, he says, will “validate the program’s ability to reduce oncology trend and improve quality of care.”

PBM, Rubinstein explains to AIS, are accustomed to adjudicating claims electronically under the pharmacy benefit, while medical benefit claims are typically not subject to electronic adjudication. With pharmacy claims, when a pharmacist keys in the patient’s information, data including the drug’s formulary status and the patient’s copayment are immediately available. But with the medical benefit, “there is no tiered drug formulary. For prior authorization, the insurer would need to write a medical benefit coverage policy instructing the oncologist, prior to use of a particular drug in all circumstances, to contact the insurer’s representative for prior authorization. Clear and definitive evidence supporting a denial would need to be documented in the medical literature — that is a high hurdle.”

**Post-Claims Review Could Be Challenge**

In addition, Rubinstein says, “post-claims review is no easier and is harder in some ways. Consider the oncologist reaction if the insurer, on Caremark/New Century advice, denies coverage for a therapy for which the oncologist billed a drug cost of $20,000. Consider if Caremark/New Century would let such a therapy get paid if it were ordered by an academically affiliated or otherwise powerful oncologist (to avoid the pushback), but denied the same prior auth or claim for a community-based oncology [practice]. Finally, it is not clear whether Caremark/New Century will monitor or share responsibility for quality of cancer care, either in objective or subjective terms.”

The CVS Caremark spokesperson tells AIS that “CVS Caremark and New Century Health will share responsibility to work collaboratively with payer clients and their network providers to define, track and measure adherence to quality indicators.”
Express Scripts Survey Takes Closer Look at Medical Specialty Spend

Specialty drug spend continued to increase, rising 19.6% from 2009 to 2010, according to Express Scripts, Inc. The main therapeutic drivers continued to be treatments for inflammatory conditions, multiple sclerosis and cancer, with these drug classes representing 68.3% of total specialty spend, up from 66.7% in 2009.

Recognizing that about half — or more — of specialty drug spend falls under the medical benefit, Express Scripts has expanded its management of the pharmacy benefit to include drugs on the medical side. In its 2010 Drug Trend Report, the PBM compared 2005 and 2008 pharmacy and medical data in some key therapeutic classes, revealing tremendous increases in spend in some classes (see chart, below). In addition, researchers for the PBM revealed that “for the first time, specialty costs (in both the pharmacy and medical benefit) comprised 25% of total drug spend and exceeded the PMPY [i.e. per-member per-year] spend in the top four traditional therapy classes.”


<table>
<thead>
<tr>
<th>Therapy Class</th>
<th>Total Spend PMPY* 2005</th>
<th>Relative % Change 2005</th>
<th>Total Spend PMPY* 2008</th>
<th>Relative % Change 2008</th>
<th>% Spend, 2008 Pharmacy</th>
<th>% Spend, 2008 Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Multiple sclerosis</td>
<td>$12.70</td>
<td>48.5%</td>
<td>$0.52</td>
<td>326.9%</td>
<td>89.5%</td>
<td>10.5%</td>
</tr>
<tr>
<td>2 Pulmonary hypertension</td>
<td>$0.86</td>
<td>115.1%</td>
<td>$0.24</td>
<td>204.2%</td>
<td>71.8%</td>
<td>28.2%</td>
</tr>
<tr>
<td>3 Infertility</td>
<td>$2.20</td>
<td>36.8%</td>
<td>$0.02</td>
<td>200.0%</td>
<td>98.1%</td>
<td>1.9%</td>
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<tr>
<td>4 Blood cell deficiency</td>
<td>$4.37</td>
<td>-27.2%</td>
<td>$9.08</td>
<td>89.4%</td>
<td>15.6%</td>
<td>84.4%</td>
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<tr>
<td>5 Respiratory conditions</td>
<td>$2.39</td>
<td>26.8%</td>
<td>$1.03</td>
<td>65.0%</td>
<td>64.0%</td>
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<tr>
<td>6 Inflammatory conditions</td>
<td>$16.30</td>
<td>60.0%</td>
<td>$8.47</td>
<td>56.7%</td>
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</tr>
<tr>
<td>7 Anticoagulant</td>
<td>$2.46</td>
<td>67.9%</td>
<td>$0.16</td>
<td>50.0%</td>
<td>94.7%</td>
<td>5.3%</td>
</tr>
<tr>
<td>8 Cancer</td>
<td>$6.48</td>
<td>77.3%</td>
<td>$35.27</td>
<td>37.3%</td>
<td>19.2%</td>
<td>80.8%</td>
</tr>
<tr>
<td>9 Growth deficiency</td>
<td>$3.99</td>
<td>48.6%</td>
<td>$0.55</td>
<td>-49.1%</td>
<td>95.5%</td>
<td>4.5%</td>
</tr>
<tr>
<td>10 Hepatitis C</td>
<td>$3.97</td>
<td>-29.2%</td>
<td>$0.08</td>
<td>-75.0%</td>
<td>99.1%</td>
<td>0.9%</td>
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<tr>
<td>Others</td>
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<td>138.8%</td>
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<tr>
<td>Total</td>
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<td>42.7%</td>
<td>$64.28</td>
<td>45.4%</td>
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</tr>
</tbody>
</table>

*PMPY = per member per year

SOURCE/METHODOLOGY: Express Scripts, Inc., 2010 Drug Trend Report, published April 2011. Data are based on an Express Scripts analysis of claims data from the Thomson Reuters MarketScan Commercial Database.
PBMs Take Aim at Much-Needed Medical Benefit Drug Management

The past few years have seen some PBMs entering the medical benefit management arena, although each has been quick to say that it is the first to offer such a service. “First is nice, especially when you are trying to preserve your current clients and impress prospects,” points out Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC. And with more than half of the substantial spending on specialty drugs occurring on the medical side, this obviously is an area that could benefit from some kind of management.

Elan Rubinstein, Pharm.D., founder and principal of consulting firm EB Rubinstein Associates, asserts, though, that “PBM entry into the medical benefit area is new,” and outcomes data seem few and far between.

In launching its program, CVS Caremark Corp. claims that “the offering is the first of its kind to provide a comprehensive management solution for the buy-and-bill drug model currently used by physicians.” Asked what aspects of the service specifically are the first of their kind, a spokesperson for the PBM declines to respond.

“This is a Caremark-driven initiative akin to what Medco [Health Solutions, Inc.] and ESI [i.e., Express Scripts, Inc.] already have been doing, as well as several other PBMs,” contends F. Randy Vogenberg, Ph.D., a principal with the Institute for Integrated Healthcare and strategic pharmacy advisor to the Business Group Pharmacy Collaborative.

Express Scripts launched its Specialty Benefit Services in 2010 — and the company claimed it was “the first PBM to bring together the three functional areas needed to comprehensively manage specialty benefits: (1) pharmacy benefit management, (2) specialty pharmacy and distribution and (3) medical benefit management.” The PBM said it saved clients $8 million during its preliminary rollout of the program last year.

In March 2008, Prime Therapeutics LLC launched Triessent, a program that included management of both the pharmacy and the medical benefit, tapping Medmark, A Walgreens Specialty Pharmacy (now known as Walgreens Specialty Pharmacy) to be its exclusive provider.

Sullivan notes that Medco began providing a similar offering in 2006 through a partnership with Healthways, Inc. According to a press release, one of the “pillars” of the partnership was “integration and analysis of real-time pharmacy, medical and self-reported data from patients and their physicians.”

According to Adam Fein, Ph.D., on his Drug Channels blog, Express Scripts is the “only one of the big three PBMs with its own distribution business for physician offices and clinics,” CuraScript Specialty Distribution. “Express Scripts is ahead of its PBM peers with an innovative and risky strategy for absorbing the buy-and-bill specialty drug spending from health care providers. If successful, the company will become the clear leader in a big new addressable market for PBM services.”

Thom Gross, a spokesperson for Express Scripts, tells AIS that “Across our book of business, we are offering our medical benefit management clients 300% to 500% returns on investment. We guarantee savings for our clients.” He adds that “health plans have been responsive and are looking at this offering in the context of health care reform. We are confident that this offer-
ing will assist managed care organizations going forward in their efforts to manage specialty pharmaceuticals covered under the medical benefit while managing medical loss ratio requirements.” In addition, he says, the company provides medical benefit management “not only for oncology medications but also for all other specialty medications billed under the medical benefit.”

Fein, who is also president of Pembroke Consulting, Inc., contends that Express Scripts’ strategy puts the PBM “on a collision course with AmerisourceBergen and McKesson for control over specialty channels to physician offices and clinics. It also sets up a battle for control over specialty drugs with the hospital systems that are busy acquiring physician practices. Put another way, Express Scripts is playing three-dimensional chess against sectors that are used to playing checkers. Biopharmaceutical manufacturers should pay close attention when designing contracting and commercialization strategies.”

“The battle for control over specialty drugs is just getting started,” he contends.

Distinguishing its offering from those of Express Scripts and Medco is CVS Caremark’s “biggest and most continuing problem in the marketplace,” contends Vogenberg. “Aside from price and theoretical benefit of retail and mail-order operations through CVS stores, they have not been able to produce meaningful results for clients nor fully differentiate their offering.”

According to Vogenberg, “Walgreens’ sale of their PBM to Catalyst underscores this issue and illustrates a clear differentiation amongst retail chain strategies in a managed care marketplace continuing to undergo change as health reform unfolds.”

Thus far, Sullivan says, Express Scripts and Medco “are strong on oral oncology but we haven’t seen sufficient evidence that they are proactive on the medical side. Actually talking with an oncologist about a treatment plan — not a single drug prior authorization — is a big leap.”

He adds that “Ironically, oncology — one of the toughest categories out there — may be the catalyst to usher in integrated medical management to high cost specialty pharmacy for much less complex disease states like rheumatoid arthritis, multiple sclerosis, etc.”

**New Express Scripts Unit Includes Medical Benefit Management**

One of the largest PBMs has created a new organization that includes medical benefit management — among the biggest areas of drug spend, as well as the least transparent — as part of its focus.

Express Scripts, Inc. is bringing together pharmacy benefit management, specialty pharmacy and distribution, and medical benefit management for a comprehensive offering: Express Scripts Specialty Benefit Services. And according to the company, in its preliminary rollout in 2010, the program saved its clients $8 million.

Matt Totterdale, who heads the new organization, points to Express Scripts’ 2009 Drug Trend Report, which estimates that “55% or more of the overall spend on specialty drugs is paid for under the medical benefit,” as helping prompt the PBM’s investment in the comprehensive offering.
The company is bringing three aspects of care together. It is making sure that patients “are at the right site of care,” says Totterdale, as well as that they are “receiving the most clinically effective and cost-effective care” for their condition. And it’s also “assisting health plans in claims management.”

Express Scripts, he says, is taking tools used to manage the pharmacy benefit and “expanding them dramatically to apply to the medical side.” With utilization management, for example, prior authorization and precertification are pieces of the approach, but it also includes quantity limits, product preferring and dispensing management with vials of drugs.

In addition, Express Scripts Specialty Benefit Services has a wholesale distribution unit through the specialty pharmacy arm, so if “the best clinical space is in the physician’s office,” the company can dispense those drugs through buy and bill, he says.

The program, Totterdale says, includes “all therapies around select disease states,” as well as “drugs used for multiple diseases or palliative care.” To determine those conditions, “we went to plan sponsors” and asked where the biggest costs were. “Oncology and palliative care around oncology” came out on top, so they were the key priorities initially. Express Scripts Specialty Benefit Services, though, is “rolling in…every drug paid for under the medical benefit, all the way down to inexpensive vaccines, which may be not high cost but are high volume,” he says.

### Program Brings ‘Line of Sight’ to Care

Totterdale contends that Express Scripts Specialty Benefit Services is the first to offer such a comprehensive solution. He explains that the company has competitors in the PBM, specialty and medical benefit management spaces, but “we are the first that has brought all three together.” The firm, he says, is “bringing line of sight” to patient care that can help detect duplicate therapies and potential drug interactions.

However, Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC, says that Medco Health Solutions, Inc. “has been offering a similar solution for several years based on a press release from May 2006 that announced a 10-year partnership with Healthways, Inc.” The program, says the release, includes “integration and analysis of real-time pharmacy, medical and self-reported data from patients and their physicians.”

F. Randy Vogengberg, Ph.D., a principal with the Institute for Integrated Healthcare and strategic pharmacy advisor to the Business Group Pharmacy Collaborative, says the formation of Express Scripts’ company “acknowledges a trend in the market and moves by Medco in this area of benefit management. It also indicates they have some catch up to do versus some competitors.”

Express Scripts Specialty Benefit Services, he says, is “not directly taking on ‘risk’ for specialty use nor really doing anything different other than perhaps a better integration of services that should have been done before anyway. It is a well-known fact the health plans don’t do a great job of managing pharmacy spend as part of medical management.”

Express Scripts Specialty Benefit Services has six clients as of late 2010, Totterdale tells AIS, and the program now is available to all of Express Scripts’ clients.

Medical benefit management is provided through Care Continuum, an Express Scripts subsidiary. The company was actually founded in the late 1990s, Totterdale says, and at that
time was “focused on the home infusion benefit, but not as much on specialty. The last several years, we’ve expanded it tremendously, and a couple of years ago, we rolled it out for our clients with a focus on specialty.”

**Company Guarantees Savings**

David Whitrap, a spokesperson for Express Scripts, confirms that the company “charge[s] for the services we provide within the medical benefit (historically through Care Continuum), similar to how we charge for the traditional PBM services we offer within the pharmacy benefit. However, it’s important to note that Express Scripts Specialty Benefit Services guarantees savings on these medical benefit services.”

In order to guarantee savings, explains Totterdale, the company uses a “proprietary analytics tool” into which it puts clients’ medical data and data from all the sites of care. Then it “runs claims based on if we’d applied our tools,” and uses that information to determine the savings. “We look at the retrospective data to charge clients on a PMPM basis and guarantee returns.”

Although the savings are different for each client, they are typically “between 2-to-1 and 4-to-1, so between a 200% return and a 400% return,” Totterdale says.

In addition, “if we were to ever not achieve our promised return on investment, our contractual agreements promise that we will pay the client the difference,” says Whitrap. So when a client adds the third leg of medical benefits to PBM and specialty pharmacy services, “the return on this investment is substantial, and guaranteed,” he says.

“We don’t make money unless clients save money,” says Totterdale.

“Savings guarantees for this sort of service are unique in the industry,” Whitrap maintains. “Our ability to offer these guarantees is based on how we’ve fully integrated the PBM, specialty pharmacy and medical benefit management. Working together, these three functions provide us the insight to uncover opportunities for additional cost savings, and the confidence to make the guarantees.”

Vogenberg explains that the program “was offered to small employers based upon ESI’s [i.e., Express Scripts] work in trend and analytics modeling that could enable pharmacy cost protection and spend predictability. In essence, this is a stop-loss related strategy where ESI buys the insurance protection as part of the PBM premium.”

According to Elan Rubinstein, Pharm.D., founder and principal of consulting firm EB Rubinstein Associates, drugs adjudicated under the medical benefit are “low-hanging fruit — lots of unmanaged and very expensive and high trend line specialty pharmaceuticals, possibly overpaid, possibly incorrectly adjudicated and certainly unmonitored.”

The program, agrees Vogenberg, is “addressing the unmanaged medical plan issues with specialty, which is a good thing and can save employers significant money.”

Sullivan points out that Express Scripts has made “no mention of requiring physicians to obtain a pre-auth for every dose administered in the office nor use a point-of-service device or computer to ‘adjudicate’ a claim as is done in the pharmacy. Since there has been little management on the medical side of the aisle, any efforts will generate savings, so the offer of a ‘guarantee’ isn’t much of a gamble.”
Still, Sullivan says, there is “that pesky thing called IT systems. In short, poking into pharmacy isn’t a problem because the PBMs handle all the data. Poking into medical claims, however, is another thing entirely — it is downright nasty.”

This is because “most payers have antiquated systems, and it is very difficult to get meaningful data from them, especially when J-codes are still part of the process,” he adds. “And, since claim submissions are usually submitted days or even weeks after the service has been provided and/or drug administered, the idea of real-time information won’t be a reality any time soon.”
Beyond Buy and Bill: Managing Specialty Therapies Under the Medical Benefit

AIS Webinar
March 29, 2011
Debbie Stern, RPh
Vice President, Rxperts, Inc.

Presentation Overview

Debbie Stern, RPh
Vice President, Rxperts, Inc.
- Medical Pharmacy Management: Payer Opportunities, Challenges and Strategies

Eric Culley, PharmD, MBA
Director, Clinical Pharmacy Services
Highmark Blue Shield
- Case Study: Strategies for Effectively Managing Specialty Drugs
Medical Pharmacy Management: Payer Opportunities, Challenges and Strategies

- Background
- Factors impacting medical specialty drug management
- Payer strategies and options

RX and Medical Benefit Crossover

RX Benefit

- Asthma
- Crohn’s Disease
- Growth Hormone
- Hemophilia
- Hereditary Angioedema
- Lupus
- Multiple Sclerosis
- Oncology
- Psoriasis
- Rheumatoid Arthritis
- Osteoporosis
- PAH
- Supportive Oncology

Medical Benefit

PAH = pulmonary arterial hypertension

Allows health plan to utilize proven cost containment tools

Harder for health plan to manage – not real time adjudication
Specialty Drug Costs by Benefit

State what percentage of your plan’s specialty drug costs fall under the pharmacy benefit and the medical benefit for each line of business.

2009 Total Drug Spend: $300B

Specialty Drug Spend: 21% = $63B

Specialty Medical Pharmacy Spend: 52% = $33B
The Number of Specialty Drugs is Increasing

New Drug Approvals: 2010

CDER NME and Therapeutic BLA Approvals (2005-2010)

Plus 6 CBER Novel Biologics = 44% Biologics and 56% NME
Orphan Drugs in Development

PhRMA: Orphan Drugs in Development for Rare Diseases, 2011.

Key Challenges Associated with Specialty Pharmacy

- Lack of standard definition for specialty pharmacy resulting in confusion to patients, payers and providers
- Products may be available under the pharmacy or medical benefit resulting in confusion about benefit design access and approvals
- Distribution channels are not consistent across the industry
- Complex management requires more time and sophisticated resources for all stakeholders

FMCP Specialty Pharmacy Initiative: A Summary of Primary Research Findings and Highlight from Eight Key Stakeholders
Comparing RX and Medical Specialty Pharmacy: Today

<table>
<thead>
<tr>
<th>Factors</th>
<th>Pharmacy Benefit</th>
<th>Medical Benefit</th>
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<tr>
<td>Benefit Design</td>
<td>• 2-4 tier benefits</td>
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<td></td>
<td>• Copay or coinsurance</td>
<td>• Coinsurance</td>
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<tr>
<td></td>
<td>• Max out of pocket per RX</td>
<td>• Annual max out of pocket</td>
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<td>• MD office</td>
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<tr>
<td></td>
<td>• Retail</td>
<td>• Home infusion</td>
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<td>Reimbursement</td>
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<td>• ASP</td>
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<td>• Medical Mgt Department</td>
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<tr>
<td></td>
<td>• Preferred products</td>
<td>• Prior authorization</td>
</tr>
<tr>
<td></td>
<td>• Step edits</td>
<td>• Post</td>
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</tbody>
</table>

AWP=average wholesale price; ASP=average sales price.

Payers are Better Able to Capture Medical Claims Data

Describe your ability to capture and process NDCs in your medical claims systems.

![Bar chart showing percentage of plans with various capabilities to process NDCs](chart.png)

EMD Serono Specialty Digest, 6th Edition
Payers are Becoming More Knowledgeable about SP Costs

2010:
RX = 98%, Medical = 75%

Payer Strategies

What Works
- Internal management of PA by RX department
- Creation of therapeutic class guidelines across benefits
- Provider reimbursement equalization

What Might be More Difficult
- Equalize cost share
- Shift all medical benefit product to RX benefit
- Mandatory use of SPP for all medical benefit products
Most Effective Strategies to Manage Specialty Drugs

On a scale from 1 to 5, where 1 = not at all effective and 5 = extremely effective, please rate the effectiveness that each of the following programs or services have had in helping your organization achieve its overall SPP management goals.

- Utilize pharmacy department to manage all specialty drugs
- Moved management of PA in house
- Implement prior authorization under RX benefit
- Mandate use of SPP for some or all SAAs
- Implement prior authorization under medical benefit
- Implement step edits under RX benefit
- Move prior authorization to SPP or other vendor

(\text{N}=85) \quad \text{Mean} = 4.03

EMD Serono Specialty Digest, 6th Edition

SAAs = self-administered agents

Reimbursement Methodology Still Varies by Provider

What is the most common reimbursement basis for specialty pharmacy products through the various distribution channels for your commercial line of business?

- \text{Home Health Care} (N=45): Cap 13%, AWP+ 9%, AWP- 51%, ASP+ 27%
- \text{Physician Office – Non-Oncologists} (N=52): Cap 13%, AWP+ 13%, AWP- 33%, ASP+ 40%
- \text{Physician Office – Oncologist} (N=52): Cap 15%, AWP+ 15%, AWP- 77%, ASP+ 42%
- \text{Retail Pharmacy} (N=50): Cap 2%, AWP+ 86%, AWP- 8%, ASP+ 4%
- \text{Specialty Pharmacy} (N=48): Cap 2%, AWP+ 90%, AWP- 6%, ASP+ 2%

\text{AWP} = \text{average wholesale price.} \\
\text{ASP} = \text{average sales price.} \\
\text{WAC} = \text{wholesale acquisition cost.} \\

EMD Serono Specialty Digest, 6th Edition
AWP Reimbursement is Leveling Out

What is the average percentage off AWP for specialty pharmacy products through the various distribution channels for each line of business?

Pharmacy Department Gaining Responsibility for all Specialty Products

Which department has the primary responsibility for overseeing the management of specialty pharmacy products for each benefit?
Mandatory Use of Specialty Pharmacy is Increasing: Pharmacy > Medical

Challenges:
- SPP cost may be higher than MD negotiated rate
- Disrupts MD workflow, especially in oncology
- Loss of buy and bill profits may need to be offset by increased admin. fees

Payers are NOT Moving OAAs to Pharmacy Benefit

Challenges:
- Pharmacy carve-outs
- Requires mandatory SPP
- Change in benefit language
Potential Industry Solutions

- Engagement of specialists in developing clinical guidelines and processes
- Decision support tools for payers and/or providers
- Re-alignment of provider incentives and fee schedules
- Evidence based guidelines across benefits

Future Challenges

- Removing all disincentives to “do the right thing”
  - Cost Share
  - Reimbursement
  - Clinical Management
  - Access
  - Distribution
- Integration of Molecular Diagnostics into coverage criteria
- Proving the value of oncology and other orphan drug therapies
Specialty pharmacy management is an evolving process....

- Payer sophistication
- Resources
- Economic environment
- Changing drug therapies

Goal of all payers, pharma, physicians, and pharmacists needs to be:

- Ensure affordable access to the appropriate patient, which results in improved health outcomes

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Fourth Tiers Could Generate Drug Savings or Increase Medical Spend

A growing number of employers are adding a fourth tier to their formularies in an attempt to rein in spending on high-cost specialty drugs, as well as lifestyle drugs, says a report released in 2010 by the Kaiser Family Foundation and Health Research & Educational Trust. But companies should consider the ramifications to employees when firms are simply cost shifting to save themselves money, or the strategy could backfire and, in fact, cost them more in the long run.

According to the Employer Health Benefits 2010 Annual Survey, 13% of companies have a prescription drug benefit with four or more tiers — almost a doubling of the total two years ago.

“Specialty drugs generally fall into the fourth tier,” says Tim Heady, CEO of UnitedHealth Pharmaceutical Solutions at UnitedHealth Group. However, he explains that his company is actually “not using the fourth tier for managing the really expensive specialty drugs. But as an example, in our current three-tier design, we look at drugs that perform clinically similarly. We end up with some of these choices in the second and third tiers. We would take some drugs from their tier and put them in the fourth to make the difference between the higher-value choice and lower-value choice more extreme.”

Higher Copays Can Boost Member Awareness

Heady says some plans’ four-tier use may be motivated by their wanting to “push more cost to employees.” He points out, though, that regardless of how many tiers a formulary may have, “there is an element of cost sharing established in any cost design.”

“Specialty/biotech drugs are very costly, and plan sponsors are realizing that increased co-pay levels, although not effective at controlling costs, increase member awareness,” says Sean Brandle, vice president, national pharmacy practice, at The Segal Company.

At UnitedHealth Pharmaceutical Solutions, says Heady, “we don’t think of using a fourth tier just to simply increase the cost to the employee, but rather we think of it based on relative value.”

He explains that when a drug is placed on the fourth tier, “it would be viewed as of less value. The idea of cost shifting versus better decision making is simply a matter of choice. If there are no alternatives, and you simply throw whatever expensive items are onto a fourth tier, that’s clearly cost shifting. If evidence supports a better value for clinical and economic choices, and you throw those on a lower tier, that is to motivate member behavior towards the better value choices. Then, if the individual spends more money, it’s by choice, not need.”

The study also revealed that fourth-tier drugs have an average coinsurance of 36%, up from 31% last year (although down from 43% and 42% in 2005 and 2006, respectively). There are a couple of ways to view this percentage, maintains George Van Antwerp, general manager for the pharmacy business at Silverlink Communications.

If a plan has a 36% coinsurance on a lifestyle drug, “as an employee, that’s great, because the plan covered two-thirds of my costs,” he says. But “if an employee has a life-threatening condition, 36% of a high-cost drug seems overwhelming.”
When drugs have “bad value,” Heady says, “we’ve been excluding them, as opposed to putting them in a fourth tier.” For example, the PBM restricted its prescription drug list to three growth hormones in January 2009, excluding four additional growth hormones that it considered therapeutically equivalent to the three on formulary.

Before the company excluded the four products, it was spending an annual average of $32,000 per member on these therapies. But following the decision, the UnitedHealth PBM reduced the annual cost by 56%.

There can be a trade-off when members’ out-of-pocket costs are so prohibitive that they forgo necessary medications, Heady contends. “We are concerned about cost, but equally concerned about [members] having access to medicines they need. Having them show up in the ER or hospital would be much more expensive” to the PBM than the drugs are, he points out.

“I would just say that the focus needs to remain on finding the right way to evaluate clinical and economic value of different drug choices and motivate behavior toward higher-value choices,” Heady says, adding that “there are just a lot of ways to approach that.”

When a formulary is “responsibly managed so that there are clinically sound choices on lower tiers, then the idea here is not cost shifting — it’s responsible cost management,” he maintains.

**Coverage of Oral, IV Oncology Drugs Can Hinder Compliance**

Although oral chemotherapy drugs can be more convenient for patients than physician-administered intravenous therapies, a variety of barriers can make access to them difficult, according to a study released in early 2010. Since about 25% of the oncology therapies in development are oral, stakeholders should consider both short-term and long-term solutions to these access issues.

For the report, Avalere Health surveyed 54 oncology stakeholders.

When it comes to patient compliance with oral oncolytics, “it’s not as easy as writing a prescription” and telling the patient to take the drug, says Patrick Cobb, M.D., president of Community Oncology Alliance, which sponsored the study. These drugs are “more targeted, less toxic and better accepted by patients” than older intravenous therapies. “But the way oral oncolytics are paid for puts an unnecessary burden on patients,” he contends.

_Oral Oncolytics/Addressing the Barriers to Access and Identifying Areas for Engagement_ examines the “fractured coverage environment” and the confusion that can arise due to inconsistencies in oral oncolytic coverage. Many plans cover these drugs under the pharmacy benefit, but some place them in the medical benefit with the infused chemotherapy drugs. Avalere noted that there is even a difference between how Medicare and some private payers cover them.

“The fact is the difference in how insurers cover oral and intravenous drugs is a big problem,” contends Cobb, who is also managing partner of Hematology-Oncology Centers of the Northern Rockies in Billings, Mont. Plans “cover intravenous chemotherapy fairly well,” he says. But “we don’t think it’s fair” that many plans push the high-cost oral drugs to the highest formulary tier and require members to pay coinsurance, which often is about 20%, while
patients receiving office-administered infusions are often responsible for only an office visit copayment.

According to Elan Rubinstein, Pharm.D., founder and principal of consulting firm EB Rubinstein Associates, having oral and intravenous oncology drugs in separate benefit structures “is a growing concern because unlike drugs administered in the office setting, oncologists do not typically have data regarding patient compliance with oral drug therapy.” High cost sharing, whether through private plans or Medicare Part D, can hinder patient compliance, he says, and with more oral oncology agents slated to hit the marketplace, “this problem will get worse.”

Cobb maintains that “the point of insurance is to share risk,” so “there should be parity between IV and oral drug” costs for patients.

However, he maintains, it is important to “make sure that the parity issue is not too blunt of an instrument. We don’t want there to be unintended consequences of covering the drugs the same,” such as imposing 20% coinsurance for both.

The study suggests four short-term solutions to the access issues:

1. **Oncologists should dispense oral oncylitics from in-office pharmacies,**
2. **Health plans either should include a medical oncologist on their pharmacy and therapeutics committees or should consult with one,**
3. **A patient’s oncology care team should include a dedicated financial counselor,** and
4. **Oncologists should take advantage of health information technology, including electronic medical records.**

Avalere also developed some longer-term areas of engagement, including the creation of a universal patient-assistance program and an oncology-specific benefit, as well as shifting oral oncylitics from the pharmacy benefit to the medical benefit.

Ideally, says Rubinstein, oral and intravenous oncology drugs “would be covered in the same benefit with the same rule set, with information going back to the prescriber regarding compliance with oral medication instructions.”

**Limits Exist to In-Office Oral Drug Dispensing**

According to Bill Sullivan, principal consultant for Specialty Pharmacy Solutions LLC, “The report is well intentioned but makes some unrealistic claims.” The first issue he cites is dispensing oral oncylitics from in-office pharmacies. “This concept is not new, and the proof of concept is that it actually works — but only for large offices with a sufficiently large patient census in multiple tumor/therapy categories to cover operating costs, which, for an oncology practice, are very large compared to a specialty pharmacy. Small practices simply do not have the volume to spread those costs efficiently, especially considering very large inventory carrying costs.”

Cobb agrees that “for one- or two-doctor practices, this is not practical.” Additional issues can arise in some states that do not allow dispensing, he says.

According to Sullivan, shifting all oral oncology drugs to the medical benefit “is counterintuitive.” Under the pharmacy benefit, claims are adjudicated using the National Drug Code (NDC) system, while the medical benefit uses Healthcare Common Procedure Coding System
J codes. “One would think that the added specificity and data tracking enabled through the NDC adjudication process would be significantly preferred to the antiquated J-code billing system, which most agree is ill-suited for care management purposes,” he tells AIS.

Sullivan also takes issue with the report’s suggestion that “the healthcare system is ill-equipped to handle the growing oral oncolytics market.” That claim, he says, “is simply wrong. Specialty pharmacies have already responded to the challenge of oral oncolytics and are very capable of providing these therapies [by] working collegially with the oncologist to enhance therapy and achieve desired clinical outcomes. Simply stated, these pharmacies have more than enough capacity to support the growing oral oncolytics market.”

### Location of Benefits Coverage for Eight Specialty Medication Classes

Although health plans adjudicate specialty drugs under both the pharmacy and the medical benefits, they are continuing to shift coverage to the pharmacy benefit, according to Health Industries Research Companies (HIRC), an independent organization that conducts market research on trends in health care, pharmaceuticals and managed care. The company’s 2010 *Specialty Pharmaceuticals Service* report includes information on how responding plans cover eight high-profile therapeutic categories.

According to HIRC, respondents say they are shifting drugs to the pharmacy benefit because of “difficulties with isolating specific medication information, tracking trends and managing specialty medication drug-spend and utilization when coverage is provided in the medical benefit. The majority of these problems are because medical claims are submitted in

<table>
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<tr>
<th>Injectable Class</th>
<th>Medication</th>
<th>Pharmacy Benefit</th>
<th>Medical Benefit</th>
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<th>Not Covered</th>
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<tbody>
<tr>
<td>Asthma</td>
<td>Xolair</td>
<td>15%</td>
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<td>Erythropoiesis-stimulating Agents</td>
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<tr>
<td>Rheumatoid Arthritis</td>
<td>Enbrel, Humira, Remicade, Rituxan, Simponi</td>
<td>87%</td>
<td>9%</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td>White Blood Cell Stimulants</td>
<td>Neulasta, Neupogen</td>
<td>28%</td>
<td>20%</td>
<td>52%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Overall Average</strong></td>
<td></td>
<td><strong>43%</strong></td>
<td><strong>38%</strong></td>
<td><strong>19%</strong></td>
<td><strong>1%</strong></td>
</tr>
</tbody>
</table>

**NOTE:** Figures are weighted averages based on commercial lives only. The Overall Average figures are averages across the eight therapeutic classes reviewed in the 2010 research. Some totals may not equal 100% due to rounding.

**SOURCE/METHODOLOGY:** Health Industries Research Companies, *Specialty Pharmaceuticals Service*, spring 2010. Research was completed from January to February 2010 with 52 HMO pharmacy and medical directors at leading health plans that represent more than 46 million commercial lives. Information was gathered via a mail survey and follow-up interviews with a subset of respondents.
many forms, from many sources, after-the-fact and often in J-codes which may be difficult to interpret and/or match 1-1 with specific medications and dosages.” Respondents contend that past shifts to the pharmacy benefit were easier because those drugs were self-administered — such as ones for hepatitis C, rheumatoid arthritis, psoriasis and multiple sclerosis — and/or physicians “didn’t have as much vested interest in buy and bill,” says HIRC. Now, however, such shifts are more difficult because of “physician resistance and administrative complications. Additionally, newly approved agents that would have been placed under the medical benefit are often initially placed under the pharmacy benefit,” says HIRC. ♦

**Plans Look to Rein In Specialty Spend by Managing Medical Benefit**

Oftentimes more than half — and possibly as much as 70% — of a health plan’s specialty drug spend may fall under the medical benefit. But with physicians buying and billing drugs they administer in their offices and using ambiguous billing codes, it can be notoriously difficult for payers not only to manage these therapies but also to even understand how much they are spending. In fact, the fifth edition of the *EMD Serono Injectables Digest* shows that of the 69 health plans surveyed, only one-third of respondents knew what they spent on specialty drugs under the medical benefit.

The Regence Group and Blue Cross Blue Shield of Rhode Island (BCBSRI) are two health plan operators taking novel approaches to managing specialty drugs in an effort to rein in spending. “In the last couple of years, there’s been a greater emphasis or need to re-evaluate how health plans structure their benefit design in covering high-cost medications because of how they cross both the prescription and medical benefit,” Lynn Nishida, director of clinical pharmacy services at RegenceRx, Regence’s internal PBM, said at a Nov. 16, 2009, AIS audio-conference. Although areas such as oncology, rheumatology, psoriasis and multiple sclerosis now have specialty therapies that fall under both benefits, health plans have not kept up with new treatment developments, she said. “What we find sometimes is health plans often structuring their benefit design for prescription benefits and medical benefits but managing [them] in silos.”

As an example, Nishida cited biologic drugs in the rheumatology category. Of 11 drugs examined — which “can cost well over $1,000 per prescription,” she noted — the five self-administered drugs are covered under the prescription benefit and the others under the medical benefit. Members may be subject to 20% coinsurance or a substantial copayment for drugs covered under the prescription benefit, but no out-of-pocket costs once the deductible has been satisfied under the medical benefit.

That incentivizes patients and physicians to game the system. If given a choice, they are more likely to use drugs administered under the medical benefit because there often is lower cost sharing and fewer administrative burdens. “There is the potential for unintended consequences and unnecessary health care costs,” Nishida warned. What’s more, under the traditional approach, a pharmacy and therapeutics (P&T) committee might review only those drugs that fall under the prescription benefit for relative value across the benefit continuum.

To address the issue, Regence has expanded the scope of its P&T committee to include specialty drugs billed through the medical benefit as well as those billed through the phar-
macy benefit, said Nishida. The committee uses medication cost integration to evaluate drugs and develop its formulary. The health plan expects to roll out the new approach in 2010. That approach “addresses all medications within a treatment category regardless of where they’re covered,” she said.

Nishida recommended treating all drugs the same, both from a P&T and a cost-sharing perspective, regardless of where they are administered. Under “medication cost integration,… we would normalize copays across the prescription and medical benefit,” so members pay, for example, $100 per specialty medication regardless of which benefit the drug is processed under. Copayments would be based on the drug’s formulary status, which in turn would be driven by an analysis of efficacy and safety data for all comparable drugs.

**Drugs Are Reviewed by Condition, Not Class**

The P&T committee has begun “to consider condition-specific reviews rather than the traditional medication classes.” For example, Nishida said, Regence wouldn’t review anti-cancer drugs such as anthracyclines, platins and aromatase inhibitors by class. Instead, it would evaluate all the drugs intended to treat a certain type of cancer, such non-small-cell lung cancer, at once. “It changed the way in which we looked at these medications overall,” she maintained. The committee also considers other care and medication costs.

Regence, Nishida said, “plan[s] to measure the success of this to make sure we achieve clear targets.” In particular, the company will look at enrollment, member and provider satisfaction and cost trends relative to those of traditional benefit design.

A few years ago, BCBSRI offered essentially unrestricted use of drugs under the medical benefit, requiring prior authorization for very few therapies, said Donna Paine, Pharm.D., the clinical pharmacy specialist at the plan and the other speaker at the Nov. 16 audioconference. Because the medical benefit was typically more favorable than the pharmacy benefit, providers and patients gravitated to it, she said. Also grappling with an outdated medical claims processing system, the plan began trying to put together a program that would change the way it managed specialty drugs.

**BCBSRI Phased In Specialty Benefit in 2008**

BCBSRI launched its specialty drug benefit April 1, 2008, and phased it in over 12 months as groups renewed. “There was not consensus for quite a while” on whether the plan should take a gradual or turnkey approach to implementation,” said Paine, who led the initiative. Although “turnkey would have been easier,” the sales and marketing employees contended that they needed time to fully explain the new benefit.

“The program was never intended to address all of the membership,” Paine explained. Fully funded groups were included in the benefit, but it was optional for self-funded groups, most of whom chose the benefit, says Paine. Medicare, Medicaid and groups that carved out pharmacy were excluded from the benefit.

Under the benefit, designated specialty therapies — both self- and physician-administered — are covered under a member’s pharmacy benefit. Members’ out-of-pocket costs for these drugs are the highest tier or coinsurance for their pharmacy benefit. BCBSRI has two pharmacies within its specialty pharmacy network, although one offers only fertility drugs. This network does not include retail pharmacies, said Paine. If members obtain a drug outside this network, “they have coverage but to a much lesser degree,” she said.
Providers who treat members with the specialty benefit must obtain drugs through the specialty pharmacy network. The specialty pharmacy must collect patients’ copayments and bill BCBSRI for drugs it dispenses. If a provider bought the drug and billed BCBSRI, the plan would deny the claim, although the provider could appeal the decision. “Provider billing for drug administration services is unchanged,” adds Paine. A prior-authorization requirement is in place for a select list of specialty drugs. And BCBSRI is in the process of switching its claims system, she said.

BCBSRI compared a year’s worth of data from people who had had the new specialty pharmacy benefit for a full 12 months with data from the 12 months prior to the program’s start. “The costs didn’t decrease, but rose less for those who had the specialty benefit,” Paine said. Per-member per-month costs increased 0.8% for groups with the benefit, compared with an 18.7% rise in PMPM costs for groups without it. And the average cost for groups with the specialty benefit rose 9.1%, while the groups without saw an increase of 13.3%. “We’re encouraged with the initial results and will continue to look at them as time goes on,” said Paine.

The initiative, though, is a work in progress. For instance, BCBSRI is working on how to engage out-of-network providers. And with physicians claiming that prior-authorization edits can be onerous, the plan is looking to see if the requirement is necessary for all the therapies that now require it, Paine explained. “We don’t want to have unnecessary hurdles.” The plan is considering new drugs to add to the program, with an eye on oncology therapies (it already includes oral oncolytics in the benefit). “But we’re not sure they can be supported in a specialty model,” she said. BCBSRI is also trying to determine how to document and quantify clinical interventions by specialty pharmacies such as efforts in waste management, side-effect management and medication adherence. ♦