



## ▶ Spending on Compounded Medications More Than Doubled in 2013

**TRENDING NOW:** Cost increases drive higher drug trend for workers' compensation

**S**ignificant increases in cost-per prescription drove drug trend for workers' compensation payers higher in 2013, according to research by Express Scripts. Overall pharmacy spending for workers' compensation increased 9.5%, according to the Express Scripts Workers' Compensation Drug Trend Report, primarily from an 8.2% jump in cost-per prescription. Effective management programs helped keep utilization increases to just more than 1%.

Compounded medications used for injured workers saw the most significant increase, with per-user-per-year costs rising 126% from 2012. Although these medications account for just 2.7% of total pharmacy costs in workers' compensation, the dramatic rise in price impacted overall trend.

"Without consistent protocols to prepare each drug, compounded drugs can have a greater batch-to-batch variability," says Tim Pokorney, senior VP, clinical services for workers' compensation at Express Scripts. "This raises significant safety concerns as injured workers could be receiving medication with a higher potency than intended."

### Other key findings:

- » Narcotic analgesics continue to be the costliest therapy class for work-related injuries, accounting for 32% of overall pharmacy costs. While utilization has declined for the third straight year, costs continue to rise.
- » Cost per prescription for hydrocodone-acetaminophen, a long-standing generic, increased 7.2%, twice the increase in 2012.
- » Non-steroidal anti-inflammatory drugs or NSAIDs, which are non-narcotic medications used to address various pains and conditions, saw a 19.4% increase in cost.
- » Specialty medications, including those to prevent blood clots following a surgery, osteoarthritis, and inflammatory conditions, make up only 1% of overall pharmacy spend in workers' compensation but pose a growing cost challenge for payers. The average cost per prescription of a specialty medication was more than \$1,119 in 2013, almost nine times that of the average traditional medication.

▼ For more information, visit [lab.express-scripts.com](http://lab.express-scripts.com).



Tim Pokorney

tively, had an OOP greater than \$1,000 for their first prescription. Conversely, about two-thirds of members starting these treatments had an OOP less than \$100.

As costs rise, the study found members are more likely to abandon their new prescription. Abandonment rates became significantly higher for both MS and BAI drugs when OOP reached \$250. Additionally, when OOP reached \$2,000 or more, the number of members abandoning their new MS prescription was almost 24 times higher compared with members with OOP less than \$100. Similarly, the number abandoning a BAI prescription was more than 19 times higher.

"This analysis indicates costs may be impacting members' ability to initiate these important treatments," says Pat Gleason, Pharm.D., director of health outcomes for Prime.

▼ For more information, visit [primetherapeutics.com](http://primetherapeutics.com).

### Developers Drawn to ORPHAN DRUGS MARKET

The global orphan drugs market presents plenty of opportunities for new drug development. Advancements in drug discovery capabilities coupled with regulatory and financial incentives are helping generate rich, competitive pipelines of breakthrough treatments with true disease modifying properties. Pharmaceutical and biotechnology companies are now rolling out therapies for serious, rare diseases as they value the financial and philanthropic rewards this brings.

New analysis from Frost & Sullivan identifies rare cancers as the orphan therapeutic area with the highest level of drug development activity. Other disease areas witnessing considerable drug development activity include blood/lymphatic system diseases, infectious/parasitic diseases, neurological diseases, metabolic diseases, and immunological/inflammatory diseases.

"In the past, pharmaceutical and biotechnology companies rarely developed new drugs to treat rare diseases because of the low return on investment realized because of the small patient population," says Frost & Sullivan Life Sciences Sen-

### Lower Out-of-Pocket Costs INCREASE MEDICATION USE

Pharmacy plan members with specialty drug out-of-pocket costs (OOP) less than \$250 are more likely to start taking their medication than those with higher OOP, according to a new study by Prime Therapeutics.

Increasing member out-of-pocket costs is a common strategy for controlling escalating costs of specialty drugs. These drugs are used to treat complex and chronic conditions and can cost tens of thousands of dollars or more per year.

The analysis of members attempting to newly start their multiple sclerosis or biological anti-inflammatory therapy found 10.5% and 9.8%, respec-

## THERAPEUTIC TRAX... ➡

## CANCER

Oncologists are optimistic that emerging targeted therapies will offer efficacy advantages over current treatment options for metastatic gastric cancer. Physicians anticipate that Roche/Genentech/Chugai's Perjeta and Roche/Genentech/Chugai's Kadcyla will join Roche/Genentech/Chugai's Herceptin in the HER2-targeted treatment armamentarium for metastatic gastric cancer.

Moreover, oncologists express enthusiasm for c-Met overexpression as a predictive biomarker in metastatic gastric cancer, and anticipate that rilutumumab (Amgen/Astellas Pharma) and onartuzumab (Roche/Genentech/Chugai), both in combination with chemotherapy, will demonstrate efficacy advantages over chemotherapy alone.

Source: Decision Resources Group, DecisionBase Metastatic Gastric Cancer: Treatment Choices are Limited, but Oncologists' Receptivity to Targeted Agents Presents a Lucrative Opportunity

▼ For more information, visit [decisionresourcesgroup.com](http://decisionresourcesgroup.com).

The effect of a therapy on overall survival and progression-free survival are attributes that most influence surveyed U.S. and European hematological oncologists' prescribing decisions for relapsed/refractory (R/R) chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). In addition, U.S. and European hematological oncologists, as well as U.S. payers indicate that improving overall survival is one of the greatest unmet needs in R/R CLL/SLL. The novel mechanism of action of first-in-class kinase inhibitors ibrutinib (Johnson & Johnson/Janssen/Pharmaceuticals' Imbruvica) and idelalisib (Gilead Sciences) has elicited great enthusiasm from interviewed experts.

Source: Decision Resources Group, DecisionBase Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Relapsed/Refractory): As the Relapsed/Refractory Treatment Setting for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Becomes More Crowded, What Key Attributes Will Differentiate Emerging Therapies According to Oncologists and Payers?

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The market value for monoclonal antibodies (mAbs) in gastric and esophageal cancer treatment is expected to double by 2019, because of favorable market conditions in terms of U.S. pricing structures and the anticipated approval of a number of late-stage pipeline drugs. The market for mAbs in gastric cancer will grow from \$256 million in 2012 to \$501 million by 2019, at a CAGR of 10%, while the mAbs market for esophageal

cancer is expected to climb from \$137 million in 2012 to \$265 million by 2019, at a CAGR of 9.9%.

Source: GBI Research, Monoclonal Antibodies Market in Gastric and Esophageal Cancers to 2019

▼ For more information, visit [gbiresearch.com](http://gbiresearch.com).

The global pancreatic cancer treatment market value in the six major countries (U.S., France, Germany, Italy, Spain, and the UK) will increase significantly from \$529 million in 2012 to \$1.63 billion by 2017, at a CAGR of 25.2%. The U.S. will show the most growth in the pancreatic cancer therapeutics market, with its total value jumping from \$275 million in 2012 to \$1.17 billion by 2017, at a higher CAGR of 33.5%. The U.S. will be followed by the five European countries, with their combined market values expected to increase from \$254 million in 2012 to \$463 million by 2017, at a CAGR of 12.8%.

Source: GlobalData, OpportunityAnalyzer: Pancreatic Cancer Opportunity Analysis and Forecasts to 2017

▼ For more information, visit [globaldata.com](http://globaldata.com).

## CARDIOVASCULAR

Servier's ivabradine (procoralan) is set to become the clinical gold-standard in the treatment of chronic heart failure (CHF). Already available in Europe, where it has enjoyed moderate use in CHF and stable angina patients, ivabradine's sound clinical profile could prime this agent for a potentially successful launch in the United States, where Amgen owns the marketing rights to procoralan.

Source: Decision Resources Group, DecisionBase Chronic Heart Failure: In the Era of Generic Cardiovascular Agents, Can Emerging Therapies Achieve Substantial Clinical Differentiation to Gain Widespread Use?

▼ For more information, visit [decisionresourcesgroup.com](http://decisionresourcesgroup.com).

## CNS

Neurologists in France, Germany, Italy, Spain, and the United Kingdom project that 16% of their diagnosed relapsing-remitting multiple sclerosis patients on average will receive Biogen Idec's Tecfidera within the next year, which is slightly higher than the 13% share they ascribe for Sanofi/Genzyme's Aubagio. Respondents indicated that future prescribing of both first-line-eligible oral disease-modifying therapies will be most encouraged through greater familiarity, improved access/reimbursement, or additional data supporting use.

Source: Decision Resources Group, European Physician and

Payer Forum report entitled A New Era for Multiple Sclerosis Disease-Modifying Therapy: EU5 Prescriber and Payer Perspectives on Current Mainstays, Recent Market Entrants, and Late-Stage Pipeline Products

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Due to upcoming patent expirations for four high-profile drugs, the global Parkinson's disease (PD) market is expected to decline from \$3.4 billion in 2012 to \$2.9 billion by 2019, at a negative CAGR of 2.3%. PD drugs, such as Azilect (rasagiline mesylate), Stalevo (levodopa, carbidopa, entacapone), and Comtan (entacapone) will lose their patents by the end of the forecast period. Generic alternatives for these treatments have already been approved, which will result in further market competition.

Source: GBI Research, Parkinson's Disease Therapeutics Market to 2019

▼ For more information, visit [gbiresearch.com](http://gbiresearch.com).

As the prevalence of Parkinson's disease (PD) continues to grow thanks to an aging population, its treatment market value is expected to increase from \$3.6 billion in 2012 to \$5.3 billion by 2022, at a CAGR of 4%. The U.S. will have the largest PD therapeutics market share of 44% by 2022, expanding from 32% in 2012. This will be followed by Japan, Brazil and Germany, with respective shares of 13%, 11% and 10%.

Source: GlobalData, PharmaPoint: Parkinson's Disease - Global Drug Forecast and Market Analysis to 2022

▼ For more information, visit [globaldata.com](http://globaldata.com).

## VACCINES

The global HPV market generated about \$1.7 billion in sales in 2012. This market is expected to experience moderate growth over the next 10 years, with anticipated sales of more than \$2.2 billion by 2022. Merck's nine-valent pipeline vaccine V503 offers protection against five additional HPV types not included in current vaccines. By 2017, V503 will be the dominant prophylactic HPV vaccine globally and will realize sales of \$1.4 billion in 2022 in the 7MM, Australia, and Canada, representing a 95% market share. This market share will largely be as a result of the cannibalization of Merck's existing vaccine Gardasil, of which sales are expected to decline significantly over the forecast period.

Source: GlobalData, PharmaPoint: Prophylactic Human Papillomavirus Vaccines - Global Drug Forecast and Market Analysis to 2022

▼ For more information, visit [globaldata.com](http://globaldata.com).

ior Industry Analyst Debbie Toscano. "Now, drug discovery for orphan diseases is becoming an important element of the business models of numerous small and large pharmaceutical and biotechnology companies looking to strengthen their presence in the global market."

As a result, pharmaceutical and biotechnology companies are introducing orphan drugs that use diverse approaches. Currently, such therapies command premium prices because of the huge clinical benefits they offer. Soon, however, they will have to be sold at competitive prices as the existing level of reimbursement will become untenable due to the anticipated approval and commercialization of several orphan drugs for neglected diseases.

▼ For more information, visit [lifesciences.frost.com](http://lifesciences.frost.com).

### Developers Are Using New Models TO BOOST CLINICAL SUCCESS RATES

Drug companies and their development partners who are seeking to increase clinical success rates of new drug candidates are developing tools to help them predict the likelihood of marketing approval and incorporating business planning earlier in clinical development, according to R&D leaders who recently participated in a roundtable discussion

convened by the Tufts Center for the Study of Drug Development.

"The research-based drug industry is racing to boost its research pipelines, as existing patents expire and development times continue to lengthen," says Tufts CSDD Director Kenneth Kaitin. "Drug companies are exploring new approaches to product development that focus on increasing the probability of clinical success and speeding time to market."

One tactic, Mr. Kaitin says, focuses on statistical models that help predict clinical success. His team, working with a pharmaceutical company, created a simple algorithmic model called the Approved New Drug Index (ANDI), modeled on the five-factor APGAR score widely used in delivery rooms to evaluate the health of newborns. This model has been able to reliably predict which oncology products emerging from Phase II testing are likely to receive marketing approval.

▼ For more information, visit [csdd.tufts.edu](http://csdd.tufts.edu).

### Oncology Patent Expirations To IMPACT NEW LAUNCHES

More than \$17 billion of sales will be at risk in 2018 and 2019 as many of the top performing oncology drugs lose their patent or exclusivity protection, ac-



Giles Somers

ording to recent analysis by Datamonitor Healthcare. By 2022 this will have grown to more than \$32 billion in sales at risk of erosion by generics. This equates to about 36% of the current cancer treatment market.

Of the top 10 selling oncology treatments, both Herceptin and Alimta will face patent expiry in the next 18 months in the European Union with Velcade the next to lose its U.S. patent in 2017.

"Oncology pipelines are rich with candidates, which is great news for patients," says Giles Somers, lead generics and biosimilars analyst at Datamonitor Healthcare. "But with so many in development, pharmaceutical companies will have to deal with either a large number of commercial failures or a more fragmented market."

He says there's a continued move toward drugs using diagnostics, which often results in smaller target populations. While this is to be welcomed, companies will correspondingly require higher prices for treatments if satisfactory sales levels are to be achieved. This can be challenging at a time when heavy costs are attracting a great deal of scrutiny and criticism.

▼ For more information, visit [datamonitorhealthcare.com](http://datamonitorhealthcare.com). PV

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