Rx Innovation Award Recipient

Prime Therapeutics LLC

Creation of “Specialty Drug Watch List” Successfully Manages Blockbusters

Title:
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Description (Problem Statement/Need/Opportunity)
The hepatitis C virus (HCV) took center stage in 2014 thanks to two new drugs by Gilead Sciences, Sovaldi® and Harvoni®, and Janssen Pharmaceuticals’ new drug Olysio®. These well tolerated, highly effective, curative drugs were positive news for approximately 3.2 million patients infected with HCV in the U.S., 70 to 80 percent of which will develop chronic infection, which can lead to liver damage, liver failure, and liver cancer. However, they came with a steep price tag that took the health care industry by surprise. Prime Therapeutics LLC (Prime), a pharmacy benefit manager serving more than 25 million members across 23 Blue Plans, saw Sovaldi move from its 13th ranked drug by total expenditures in January 2014 to its top drug in April 2014 with $51 million in expenditures. Prime predicted this prescription wave could increase the HCV cost burden on commercially insured health plans by as much as 800 percent in 2014. With the full cost to treat HCV at more than $100,000 per patient, and additional drugs by other manufacturers on the horizon, aggressive management was a must. Prime set out to completely change how it approached drug launches through research, operational changes and communications with its health plan clients.

Target Audience(s):
Primary: Prime’s health plan clients (i.e., CEOs, pharmacy & medical directors, CFOs, actuarial teams, sales, marketing, account management, contact centers, etc.), Prime leadership and client engagement
Secondary: Media, members, brokers/consultants, Managed Care Organization prospects, doctors/pharmacists (through the Plan, if applicable), policymakers, all Prime employees

Objectives:
Recognizing the HCV treatment wave could severely harm the financial stability of its health plans and their members, Prime created the Specialty Drug Watch List. This Watch List serves as an early warning tool and supplies actionable clinical intelligence to clients about blockbuster drug launches.

Using the HCV drug class as an example, specific objectives of the Watch List were:
1. To help clients control costs and achieve a negative HCV drug cost trend in 2016, by:
   a. building a cost forecast model based on actual testing rates and new diagnosis incidence using medical claims data as opposed to population-based estimates, and
   b. improving operational readiness, e.g., adopting “fast path” utilization management strategies.
2. To increase timely, proactive communication about drug approvals among more audiences at the health plan clients, to inform budgeting discussions, and improve utilization management decisions.
3. To help eligible members afford the medicines by ensuring cost share per month is less than $250 for 95% of HCV drug prescriptions dispensed from Prime Therapeutics Specialty Pharmacy.

Implementation Plan or Methodology, Resources and Metrics:
Objective 1: To help clients control costs and achieve a negative HCV drug cost trend in 2016
Understanding Testing, New Diagnosis, and Treatment Rates
Creating the most accurate use and cost trend forecasts for new HCV drugs first required an understanding of the testing and treatment rates in a commercially insured population. Prime researchers analyzed their medical and pharmacy claims data and published “Incidence Rate of HCV Screening and New Diagnosis in its Commercially Insured Population.”
Understanding testing rates is important because chronic HCV virus infection is a serious public health problem with a large number of individuals who do not know they are infected.

Methodology: Prime analyzed approximately 12 million commercially insured members of which 5 million were continuously insured January 2011 to April 2014. The earliest claim in this interval was identified for each member for: a) HCV antibody screening, b) anti-HCV drug treatment, and/or, c) a diagnosis code for HCV. The incidence of first screening was quantified for three 10-month intervals: (1) before CDC (Oct 2011 to July 2012), (2) after the CDC (Aug 2012 to May 2013), and (3) after USPSTF (Jul 2013 to Apr 2014) recommendations.
To identify members with a HCV diagnosis, Prime used an analysis of the 5 million continuously enrolled members from January 2011 through May 2014, looking for at least one medical claim carrying an International Diseases Classification – 9th version (ICD-9) code of 070.41, 070.44, 070.51, 070.54, or 070.7x. The prevalence of members with HCV diagnosis among continuously enrolled was then extrapolated to the entire commercially insured in May 2014, by state.

Results: Prime found the estimated number of new diagnoses resulting from screening for the whole population was 1.60, 1.94, and 1.97 per 100,000 members per month in the three 10 month intervals. Using the estimated testing, diagnosis rate, and flat trend, Prime forecasted two (2) new members with a HCV diagnosis per 100,000 members per month for 2015 and 2016 would be identified. The current count of members with a HCV diagnosis was quantified to be 42,284 among Prime’s 14.8 commercially insured members, as of December 2013.

Conclusion: Testing of older members and new diagnosis of HCV infection increased following the announcement of new guidelines, but remains low, and has been flat in the past year. These testing and new diagnosis rates can be used to forecast future HCV drug therapy utilization rates among commercially insured individuals. By employing the above sampling of medical claims data, Prime found the industry predictions of an expected continued rise in testing was not true for commercially insured populations.

Modeling Use and Cost trends
Prime researchers built a HCV drug therapy utilization and cost forecast.

Methodology: Prime created a HCV new treatment start rate and per member per month (PMPM) cost forecast with the following input variables:
- Pharmacy claims data through May 2015
- HCV current diagnosis prevalence
- HCV testing rate and new HCV diagnosis data remains stable
- Average actual HCV drug treatment cost of $122,000 using member treatment data from December 2013 through May 2014. This incorporates all drug therapy regimens and durations of therapy.
- Assuming no price HCV price inflation in 2015 and 2016
- Assuming the future HCV drugs approved are price parity – $122,000 treatment regimen
- Assuming a retreatment rate of 10%

Results: Prime researchers forecasted HCV to be present in 48,208 of Prime’s commercially insured members by 2015, an additional 6,000 members in just two years. For Prime’s commercially insured book of business consisting of 14.8 million members, the HCV drug class per member per month cost increased from $0.38 in 2013 to $4.28 PMPM in the month of April 2014.

Conclusion: Looking ahead, Prime predicts total costs for their commercially insured population will have increased 800-850% by end of 2014 over 2013 costs. In 2015, it will continue to increase another 20-50% over 2014 costs as more new products launch, and then decline by 20-40% in 2016 over 2015 costs.

Improving operational readiness
Another key element, in achieving the first objective of helping clients control costs, was to improve operational readiness for managing HCV drugs. Prime took the following steps:
- Implemented New “Fast Path process” and designation to high impact drugs. This enables Prime to have utilization management (UM), such as prior authorization and step therapy criteria, developed, reviewed and approved by the plans in advance of a drug launch. Implementation of UM now occurs within five days of a drug launch compared to the 60 to 90-day standard process.
- Held off-cycle P&T committee meetings. Should a drug receive approval far in advance of its estimated Prescription Drug User Fee Act (PDUFA) date, the date when the FDA begins collecting fees to cover the drug approval process, P&T committee members can convene off-cycle to determine appropriate management strategies.
- Revised trend impact estimator. For all medications on the Watch List, a cost impact indicator ranging from $ to $$$$ will help clients anticipate a particular drug’s PMPM impact on the medical or pharmacy benefit and whether or not it is new spend or shifting from one benefit to the other.
- Evaluated new products and worked with manufacturers to leverage discounts (ongoing). As more competition enters the HCV market, Prime plans to implement a preferred product strategy at the beginning of 2015.

In addition to the operational enhancements listed above, Prime traditionally recommends using the following levers to manage this drug class: Benefit Design, Care Management, Prime Specialty Pharmacy, Formulary Management, and Utilization Management.

Objective 2: Increasing proactive communication
To aid clients in making utilization management decisions about blockbuster drugs that ultimately impact budgeting and establishing premiums, the following communications strategies were deployed:
- Comprehensive communications strategy. Prime now provides progressively more communication as a drug’s impact increases. Market Alerts for clients, talking points for client engagement teams/sales/contact center representatives, marketing collateral, board member emails, press releases/statements, blog posts, webinars, member materials are all examples of tactics that can be leveraged to inform our public as warranted.
- Broader audience reached. In addition to pharmacy teams, finance, sales, marketing, communications and member services teams at our Blue Plans may receive information about anticipated cost implications and management recommendations.
This proactive communications approach allows Prime to be more consultative with clients. When the FDA approved Harvoni, Gilead’s newest HCV drug, on October 10, 2014, Prime was ready:

- Prime’s CEO emailed board members to provide details about the drug in advance of its approval
- Prime sent a market alert to all our clients
- Prime’s monthly webinar with client pharmacy teams included information about Harvoni
- Prime’s sales and client engagement teams were provided talking points and marketing pieces
- Prime distributed a press release about Harvoni and conducted media interviews

**Objective 3: Helping eligible members afford the medicines**

To achieve the third objective “to help eligible members afford their medicines,” Prime works to ensure cost share per month is less than $250 for 95% of HCV prescriptions dispensed from Prime Specialty Pharmacy. It does this through:

- **Care management programs.** Administered by a team of pharmacists, nurses, care coordinators and insurance specialists, includes outreach to members encouraging adherence and side effect management, while identifying and removing barriers to treatment regimens.

- **Cost-share set at a rate that encourages adherence.** This is important as specialty medicines are expensive (e.g., Sovaldi® $1,000 per pill). As member out-of-pocket rises above $250 per prescription, patients are more likely to abandon their new prescription, according to Prime research.8

- **Access copay offset programs (as appropriate for preferred products).** Copay coupons and patient assistance programs for specialty medicines can reduce out-of-pocket costs for members. Prime Specialty Pharmacy’s copay offset program helps reduce costs of preferred specialty drugs.

Prime gained valuable experience managing HCV, and quickly expanded the innovative Watch List forecasting, and methodology behind it, to several other drugs coming to market in late 2014 and 2015 (i.e., Esbriet® and Ofev® for idiopathic pulmonary fibrosis, secukinumab for plaque psoriasis, and palbociclib to treat breast cancer). As a result of the Watch List, Prime’s clients and members are well-prepared to manage other high cost, high use medicines and best serve their members.

**Evaluation and Results:**

**Client Cost Control**

By deploying a Watch List approach for HCV, Prime’s Blue plan clients were able to take proactive comprehensive management steps that trimmed their HCV drug costs by 38%!

Through the first three quarters of 2014, Prime saw roughly $407 million in HCV drug expenses among 14 million Prime commercial lives. Internal analysis of the HCV drug utilization and net per prescription paid compared to the projected utilization and average wholesale price for all HCV drug claims that would have been paid without the Watch List management strategies in place, shows Prime’s comprehensive efforts helped our health plan clients achieve a 38.2% on HCV drugs. The picture would have been much worse had Prime not deployed a combination of these management strategies:

- contracting activities (i.e., rebates from manufacturers)
- distribution channels (i.e., distributing through Prime Specialty Pharmacy)
- utilization management (i.e., prior authorizations)
- care management (i.e., coordination with health plan case and disease managers, adherence programs, side effect management, etc.), and
- copay offset programs (i.e., specialty copay coupons and patient assistance programs).

Specifically, Prime’s prior authorization (PA) program saved more than $7.6 million in costs between April 1 and June 30, 2014. This equates to a savings of approximately $0.59 PMPM. Only after thoroughly evaluating our data and finding specific scenarios that would benefit from their use, does Prime develop PAs to manage drug safety and appropriate treatment. Prime’s Q2014 data shows roughly 20% of HCV drug requests are not approved (i.e., denied) because the patient does not meet the clinical requirements. While denial rates can be as high as 50% in plans with high HCV prevalence rates and more stringent criteria, 20% non-approval is in line with rates Prime sees in other specialty drug classes.

**Member Adherence**

With HCV treatment regimens averaging $122,000, it’s critical members stay adherent or that money is simply wasted. Through Q3Q2014, Prime’s commercial book of business showed 92% of members had a drug supply to complete a 12-week course of a HCV drug therapy. That translates into an 8% discontinuation rate. This low discontinuation rate signals strong adherence and Prime Specialty Pharmacy’s high touch care management efforts contributed to this success.
Communications Enhancements
Measuring the efforts of improved communications can be difficult or anecdotal in nature, but certainly is essential to understand if perceptions are having the desired effect. Since launching this effort, Prime:
• added new communication vehicles such as client webinars on forecasts, weekly drug newsletter, Market Alerts on drug approvals, FAQs and a HCV Strategies overview brochure
• delivered communications well in advance of a drug’s FDA approval compared to at time of approval
• received coverage in various media channels and spread the word on social media (i.e., when Harvoni received approval from the FDA on October 10, Prime issued its perspective a press release within the hour of the announcement)

The best measure of our new communication approach came from client feedback. Blues plan CEOs demonstrated their awareness and positive response at the recent board meeting. Other key client contacts have shared they have appreciated receiving more timely information that they can take action upon, saying:
• “Nice finish….. glad to see the rapid response on this!”
• “This is definitely the information we need upfront to make critical business decisions”
• “These communications are very helpful and we appreciate the extra efforts to keep us on top of new drug launches that may have significant impact on our business”

Member Savings
And members saved, too! January 2014 through September 2014, Prime Specialty Pharmacy secured more than $30 million in copay offsets for all specialty drugs. For Sovaldi, the picture is also substantial. Approximately 55% of members (641 of 1,167) who filled Sovaldi through Prime Specialty Pharmacy had a coupon applied to their prescription, saving each member an average of $610 per Sovaldi prescription.

References: