



## Specialty Pharmaceutical Risk Mitigation

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Jan 14, 2011



Nationwide, specialty drug spending continues to grow by double digits – 15% to 20% in 2009, and an estimated 22% to 25% in 2010. Total drug spending in the United States in 2009 was just over \$300 billion, with specialty drugs representing 21% of the total, or approximately \$63 billion. Important to understand is that only 1% to 2% of the population accounts for this spending. By isolating a smaller bucket of risk – namely the population vs. the spending category – self-funded plans can more effectively protect against identifiable risk factors.

### Risk Management vs. Risk Mitigation

Standard measures used to manage specialty drug spending include member cost-sharing, step therapy, pre-authorization, evidence-based coverage guidelines, and various case management and utilization management programs. While necessary to manage the growth in spending, each of these tools fails to predict which drug(s) or member(s) are more likely to scrape the boundaries of affordable risk. In real terms, these measures can be characterized as reactionary attempts to minimize an already-born risk. Indeed, they do not minimize the risk itself or adequately account for its foreseeable cost.

The majority of specialty drug spending resides in the large therapeutic categories of cancer, multiple sclerosis and inflammatory conditions. But it is in rarer therapeutic categories where unpredictable "blips" (or "left hooks" depending on the size of the plan) in spending are more likely to threaten existing risk management protections, and thereby present true financial risk. Drugs for the rarest diseases inevitably carry a higher per-patient price tag, but spending "blips" can also be due to fewer drugs being available within a therapeutic class (limiting formulary or step-therapy options), the incurable nature of a disease (resulting in few, if any, treatment alternatives), the unpredictable duration of therapy (limiting standard authorization guidelines), or the existence of limited drug distribution network (affecting negotiated price discounts).

Each therapy category presents its own unique opportunity for risk mitigation, but the smaller the therapy population, the more precise (and effective) your mitigation strategies will usually be.

### Examples of Risk Mitigation Strategies

A good example is hemophilia – a \$2 billion category of annual drug spending incurred by approximately 17,000 people nationwide. Inherent within any hemophilia population is stratifiable financial risk – based on disease type, severity, age, weight, and other factors. While the average cost of anti-hemophilic clotting factor medication is approximately \$130,000 per patient per year, the median spending is closer to \$40,000. Depending on the combination of risk factors, a hemophilia patient's use of clotting factor medication may cost as little as \$1,000 per year, or as much as \$3 million or more. In some cases, the drug cost for one individual with hemophilia can swing hundreds of thousands of dollars per year.

A small self-funded plan with four hemophiliac members could estimate average annual costs of \$130,000 per patient per year, but may fail to recognize that one of those members is likely to develop an inhibitor (antibody) to clotting factor which could increase predicted factor therapy costs three-fold. By mapping this population according to its risk parameters, a self-funded plan can uncover opportunities to either capitate or share risk, or take proactive steps toward cost-prevention, such as "off schedule" pricing or various patient education and adherence training initiatives on the front-end.

Immunoglobulin (Ig) therapy is another example, with an estimated \$4 billion drug category affecting approximately 1 in 4,000 lives. With an average annual cost of \$40,000 per patient, Ig therapy has been used to treat over 100 acute and chronic conditions, including primary immune deficiencies, secondary immune deficiencies, autoimmune disorders and neurological disorders. Average spending among the different disease groups ranges between \$10,000

and \$1 million per year. Ig has been safely and reliably infused in a homecare setting for decades, yet the vast majority continues to be infused in the more costly setting of a hospital or outpatient infusion center.

With the wide variety of conditions treated with Ig, the financial risk of the therapy cannot be reliably predicted based on a pure diagnostic population analysis. However, future expenditures for existing Ig therapy "outliers" often can be predicted. This involves an analysis of an Ig patient's risk profile, including diagnosis(es), site of care, age, weight, and previous treatment history. It is a member's risk profile that predicts the anticipated frequency and volume of drug to be used, the payable drug price (based on plan design and site of care), the anticipated duration of therapy, and the likely outcome of treatment – all important elements to establishing the boundaries of financial risk and instituting cost avoidance measures where they will have the greatest impact. These measures might include options such as case-rate (single member) capitation, "off schedule" drug pricing and rebates, or targeted disease management strategies and provider partnerships where high-dose Ig prescribing is the norm.

### Summary

Self-funded plans – especially small- and medium-sized – can be better prepared with a specialized review of their specialty drug populations. In contrast to standard pharmacy and medical management efforts to control the rising cost of specialty pharmaceuticals, by proactively analyzing their specialty drug populations, self-funded plans can explore unique opportunities to prevent unnecessary risk and/or cap predictable drug expenditures – a true risk mitigation strategy. Waiting until a pharmacy calls for pre-authorization is not the time to recognize the extent of your future drug spending. A risk mitigation strategy attempts to undermine predictable catastrophic expenditures. With even a small dent in a high-cost member's claims, self-funded plans can quickly save hundreds of thousands, if not millions, of dollars per year.

### About the Author



**Eric Hill** is Vice President of BioRx, LLC, a specialized provider of pharmacy and infusion services targeted at extremely high cost, low prevalence, chronic diseases – typically with an annual drug spend of greater than \$50,000, but up to \$1 million or more. Mr. Hill has more than 20 years experience in the specialty pharmacy/infusion industry. Under his leadership, BioRx has created innovative pricing and risk assumption strategies for catastrophic specialty pharmacy patients, including single-patient case rates and capitation agreements.

BioRx employs a centralized drug distribution model coupled with decentralized customer and clinical service. This combination delivers high-touch, therapy-specific services to the patients who need it most, while ensuring consistent quality pharmacy service and clinical care. The company's core areas of focus include hemophilia clotting factor, immunoglobulin, C1 esterase inhibitors (for hereditary angioedema), alpha-1 proteinase inhibitors (for alpha-1 antitrypsin deficiency), and parenteral nutrition.

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