



High-cost pharmaceuticals

Their effect on self-funded medical plans

Traditionally, large or catastrophic stop loss claims were incurred as a result of lengthy hospital stays and associated charges. Today, pharmaceutical charges alone can lead to these claims.

Without question, we're in a time of great medical innovation. Leading the way is the rapid expansion of biologics and specialty pharmaceuticals designed to treat a wide range of health conditions. While these new medications are exciting developments for patients and their families, the exponential rise in pharmaceutical costs can quickly overwhelm the budgets of any employer group—whether self-funded or fully insured.

In this issue of the Inside Track, we'll provide a general overview of high-cost pharmaceuticals and discuss how charges for these types of prescriptions can affect self-funded medical plans.

What are high-cost pharmaceuticals?

The medications in this discussion generally fall under three categories: biologics, specialty pharmaceuticals and compound drugs.

- **Biologics** are diverse, complex products for the treatment, diagnosis and prevention of a broad range of common and rare diseases.¹
- **Specialty pharmaceuticals** are often biologics. They are oral, injectable, inhalable or infusible drug products used to treat more complex or chronic medical conditions.
- **Compound drugs** are prepared by a pharmacist—or someone under the supervision of a pharmacist—who combines, mixes or alters the ingredients of a drug to create an individualized medication for a specific patient.

High-cost pharmaceuticals are structurally complex and used for conditions such as multiple sclerosis, hepatitis C, rheumatoid arthritis and cancer. These medications are typically dispensed by a self-funded plan's pharmacy benefit manager (PBM). However, they may also be supplied by other pharmaceutical providers to be administered in a clinic, home or hospital setting.

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Examples of high-cost pharmaceuticals. Actual costs vary by patient.²

Name	Description	Annual Cost Range
Soliris/eculizumab	Used for Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS) and Generalized Myasthenia Gravis (gMG), this drug is administered indefinitely every two weeks.	\$625,000 to \$1.3 million per year
NovoSeven RT; ADVATE	Used to treat Hemophilia A or B with inhibitors, Acquired Hemophilia, Congenital Factor VII Deficiency and Glanzmann's Thrombasthenia. Regular infusions of the clotting factor drug can help prevent bleeding.	\$550,000 to \$1.8 million per year
Aldurazyme/laronidase; ELAPRASE/ idursulfase	Used to treat one of the subsets of mucopolysaccharidosis, a group of metabolic disorders. There are several types of mucopolysaccharidosis, each with a different drug to treat the disease.	\$200,000 to \$1 million per year
Berinert/C1 esterase inhibitor; FIRAZYR/ icatibant; KALBITOR/ ecallantide; CINRYZE/C1 esterase inhibitor	Used to treat Hereditary Angioedema (HAE), a rare and potentially life-threatening genetic condition which causes swelling in various parts of the body.	\$450,000 to \$800,000 per year
Juxtapid/lomitapide	Used to treat Homozygous Familial Hypercholesterolemia, an inherited condition that causes high cholesterol levels (LDL) beginning at birth.	\$700,000 to \$750,000 per year
Kymriah/tisagenlecleucel	Used to treat refractory acute lymphoblastic leukemia (ALL) and relapsed or refractory B-cell lymphoma in patients 25 and under using their own white blood cells.	\$475,000 per treatment
Yescarta/axicabtagene ciloleucel	Used to treat relapsed and refractory non-Hodgkin lymphoma in adult patients using their own white blood cells.	\$373,000 per treatment
Zolgensma/onasemnogene abeparvovec-xioi	Used to treat spinal muscular atrophy in pediatric patients less than 2 years of age.	\$2,125,000 for a one time infusion ³

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Growing market, increased costs

Many factors have influenced the speed at which biologics and specialty pharmaceuticals are entering the market and the sudden surge of utilization and cost.

- Direct advertising by pharmaceutical companies has increased awareness of certain medications among consumers, who may pressure providers to prescribe one formula over another.
- Research and development expenses are significant for manufacturers who need to create a multitude of formulas before finding one that works.
- Manufacturers are incentivized by the FDA to develop “orphan” drugs to treat rare conditions. These medications are costly because there is a smaller distribution base and they generally must be dispensed by a specialty pharmacy.
- An increasing trend of medication being prescribed for uses other than what the FDA has approved has led to increased utilization of certain high-cost drugs.

Additionally, many physicians prefer to recommend the newest—and usually more costly—treatment option, bypassing traditional methods that could be just as effective and less expensive. Stronger checks and balances by the plan sponsor and claims administrator can help ensure these options are used appropriately to keep costs in check.

The role of the pharmacy benefit manager (PBM)

Pharmacy benefit managers (PBMs) are responsible for processing and paying prescription drug claims. Since pharmaceutical charges are not administered with a self-funded plan’s medical benefits, the PBM is generally focused only on the pharmaceutical portion of an insured’s treatment plan.

When looking for a PBM to partner with, it’s important to understand what services they provide to help manage the cost and utilization of prescription drugs. Things to consider include:

- Do they contract with a large network of pharmacies?
- What specialty pharmacy and distribution services do they offer?
- Does their disease management program ensure patient compliance?
- Do they perform drug utilization reviews?
- Will they adhere to provisions in the employer’s plan document regarding generic, formulary brand name and non-formulary drugs?
- Do they recognize that most compound drugs are not FDA approved and may be excluded by the employer’s plan document?
- Are they transparent when it comes to drug cost pricing and manufacturer rebates?

It is critically important that the PBM vendor contract is aligned with the employer’s plan document. Check to ensure that provisions allowing cost-effective treatment options (e.g., step therapy) are explored first. Confirm that language regarding the use of generics and the payment of formulary and non-formulary drugs is clear. Finally, if any PBM rebate is offered, the amount should be disclosed upfront to ensure the stop loss policy pricing is adjusted accordingly and claims are reimbursed appropriately.

Stronger checks and balances between the pharmacy benefit manager, medical providers and the stop loss claims administrator can help mitigate high-cost pharmaceutical charges.

The effect on self-funded medical plans

From a self-funded employer's perspective, the prevalence of biologics, specialty pharmaceuticals and compound drugs has increased the frequency of prescription drug claims at higher dollar amounts.

Due to the inconsistency in how providers bill for these pharmaceutical expenses, some drugs are covered under a self-funded employer's prescription drug plan while others are covered under the medical plan. These variances stem from where medications are administered—a hospital, a doctor's office, or under supervision at home. As a result, charges may be filed under different service codes, which can directly impact the self-funded plan's budget.

The high cost and complexity of these drugs, as well as lack of consistency in billing practices, highlights the importance of validating such charges and managing them effectively. Plan sponsors should have guidelines outlining when and how they review prescription drug charges. And claims administrators must work closely with the prescribing physician to ensure all treatment plans and records are up-to-date.

High-cost pharmaceutical management for self-funded groups

Self-funded employers have access to a number of resources that can help ensure that plan participants receive the best possible care, and that billed charges—including those for biologics, specialty pharmaceuticals and compound drugs—are reasonably and appropriately priced.

- **Specialized stop loss brokers and/or consultants** play a vital role due to their knowledge of self-funding and medical stop loss coverage. They can help ensure that plan documents contain the necessary provisions for managing pharmaceutical expenses and clearly state what is eligible and reasonable under the plan. They will also ensure the employer's claims administrator and stop loss carrier can diligently safeguard the plan's assets.
- **Claims administrators** should have case managers who can work with patients and physicians to validate the appropriateness and cost effectiveness of high-cost pharmaceuticals.
- **Stop loss carriers** provide insurance coverage for large pharmaceutical claims and can access cost-containment vendors that validate the appropriateness of billed charges and treatment plans. Leading stop loss carriers will also provide a second review of claim payments to confirm plan provisions were satisfied, and work with clinical experts such as RN professionals who can assist with complex or questionable care options. In the event of a high-cost prescription drug claim, an RN can work with the plan's claims administrator to evaluate whether a prescribed medication is truly appropriate for a particular patient.

Collaboration is key

The innovation and effectiveness of today's pharmaceuticals is impressive, but the cost can be overwhelming. By working as a team with their broker or consultant, their stop loss provider and a pharmacy benefit manager, self-funded employers can strike a balance between providing care that prolongs or enhances the lives of employees and managing their bottom line.

For more information on high-cost pharmaceuticals and self-funded medical plans, contact your stop loss representative.



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¹ Source from Overview of Biological Products PowerPoint. Retrieved March 19, 2018. <https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM356666.pdf>.

² Source: Symetra Excess Loss Policy claims data, 2018.

³ Drug manufacturer offers a pay-over-time model and has established outcomes-based agreements with payers to allow a payment plan of \$425K/year for five years.