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The Groundbreaking Science Impacting Large Medical Claims

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It is not news that large medical claims are on the rise, with organ transplants, cancer and congenital anomalies being common drivers. But the real drivers of multimillion dollar claims are likely to come in the innovative new treatments that are being developed right now. Understanding what is coming down the Food and Drug Administration (FDA)-approved pipeline is the first step towards being adequately prepared. With the prospect of more innovation driving high cost medical claims, insurers have options to help them prepare.

Gene Therapy

Gene therapy has been getting a lot of attention from insurance carriers and employers lately, as innovative new treatment methods are poised to change the way a range of serious conditions are treated. Gene therapy is a general term for a medical treatment that involves injecting engineered viruses that contain healthy genetic material into a cell that contains mutated genes, thereby "correcting" the faulty, disease-causing gene. It has the potential to revolutionize treatment for diseases that currently have no cure, such as cystic fibrosis and sickle cell disease, and eventually for non-congenital diseases such as cancer. Scientists are even investigating prenatal gene therapy for select conditions.

Most recently (May 2019) the FDA approved Zolgensma (by Novartis), the first gene therapy for a neuromuscular disease. The cost is expected to be USD 2.1 million. Pharmaceutical companies Sarepta and Pfizer have been racing to bring a gene therapy cure to market for a rare, genetic muscle-wasting disorder that affects about one in every 3,500 to 5,000 males. Trials of the Pfizer method raised safety concerns, while Sarepta's data has been more promising — the company has even commercialized a treatment, Exondys 5, for one form of the disease.

Many genetic therapies are considered to be experimental treatments, but it is only a matter of time until they enter the standard of care, further pushing the "status quo" threshold of large medical claims. Who will pay, and how, must be addressed.

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Hemophilia Treatments

Hemophilia is a congenital disorder that inhibits the body's ability to form blood clots, leading to spontaneous bleeding, bruising or excessive bleeding following injuries. Around 400 babies are born with hemophilia each year, making this a rare disease that currently affects around 20,000 Americans. Two types exist — Hemophilia A and B — determined according to the specific protein that is missing from the blood. Hemophilia A is more common.

Traditionally, hemophilia treatments have involved regular injections of the missing blood-clotting factor — treatments that are time consuming, expensive and invasive. Gene therapy stands to change that. While still in the experimental phase, these new treatments insert functional copies of the gene for clotting factors directly into the patient's cells, letting their bodies produce their own clotting protein. This would either reduce or completely eliminate the need for repeat treatments, depending on the severity of the patient's condition.

SPK-8016 (Spark Therapeutics and Pfizer), AMT-061 (uniQure) and ValRox (BioMarin) are three such treatments currently in either phase 2 or phase 3 trials with the FDA. Clinical studies have been promising, with no adverse effects recorded, but it is still too early to tell if the therapies represent a lasting cure. What is certain is that scientists are on their way to permanently changing the way this disorder is treated.

High-Cost Injectables

Hereditary angiodema (HAE) is another rare disease that currently has no definitive "cure," but is the reason for a small but growing number of catastrophic claims. HAE is caused by a genetic defect that produces swelling in the body, typically affecting the patient's hands, feet, face and throat, causing pain, vomiting and potentially even death by asphyxiation due to the swelling of the airway.

According to the U.S. Hereditary Angioedema Association, HAE affects one in every 10,000-50,000 people, with a death rate of 15–33 percent for patients. Difficult to diagnose and complex to treat due to the wide variability in symptoms and severity, the past 10 years have seen a wave of injectable drugs that fight life-threatening swelling. Those injectables have been steadily increasing in price — as much as USD 10,000 per injection — so that a patient suffering from the disease can consume millions of dollars in treatment each year, emergency room visits included. HAE is just one prominent example of a disease now being treated by high-cost specialty drugs.

While these innovations are a great benefit to society, their development begs the question of who and how they will be paid for. With new therapies expected to cost

USD 1 million or more, the impact to employer and plan healthcare spend will be significant. Currently, drug manufacturers are considering treatment finance options. Insurers are thoughtfully approaching the issues, with many considering options including cost-containment strategies such as bundling services with providers to achieve discounts and outcome-based reimbursements to providers and drug manufacturers. However, there have been no definitive conclusions on these fronts.

Guy Carpenter continues to monitor new developments in the high-cost drug market. We can help carriers prepare themselves to best manage the costs as new risks emerge, and provide solutions to drive business results. Our solutions, together with the world's most advanced analytics, help clients face a rapidly changing risk landscape with confidence. Please contact us if you are interested in learning more.