

# Rx newsletter

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# Market trends

## Understanding value-based health care models

Value-based health care models are a departure from the traditional fee-for-service system, focusing on delivering high-quality care while controlling costs.

These models prioritize patient outcomes and experiences, aiming to provide the best value for patients and payers. By incentivizing health care providers to deliver efficient and effective care, value-based models have the potential to transform health care delivery and improve population health outcomes.

### Data & Analytics

Data and analytics are integral to the success of value-based health care models. By harnessing the power of data, health care providers can effectively measure and improve performance, identify areas for enhancement, and make evidence-based decisions. Numerous studies have demonstrated that hospitals participating in value-based payment programs have shown improvements in quality scores, highlighting the positive impact of data-driven approaches.<sup>1</sup>

Pharmacists play a vital role in value-based health care models due to their accessibility to patients, extensive knowledge of medication therapy, and ability to provide health care services beyond medication dispensing. Pharmacists can focus their efforts on medication therapy management (MTM), chronic disease management, and preventive care and immunizations.

While the adoption of value-based payment arrangements has steadily increased, recent reports indicate a slowdown in growth. According to the Health Care Payment Learning and Action Network, the percentage of health care payments tied to value-based models experienced stagnant growth from 2021 to 2022.<sup>2</sup>

### Care Coordination

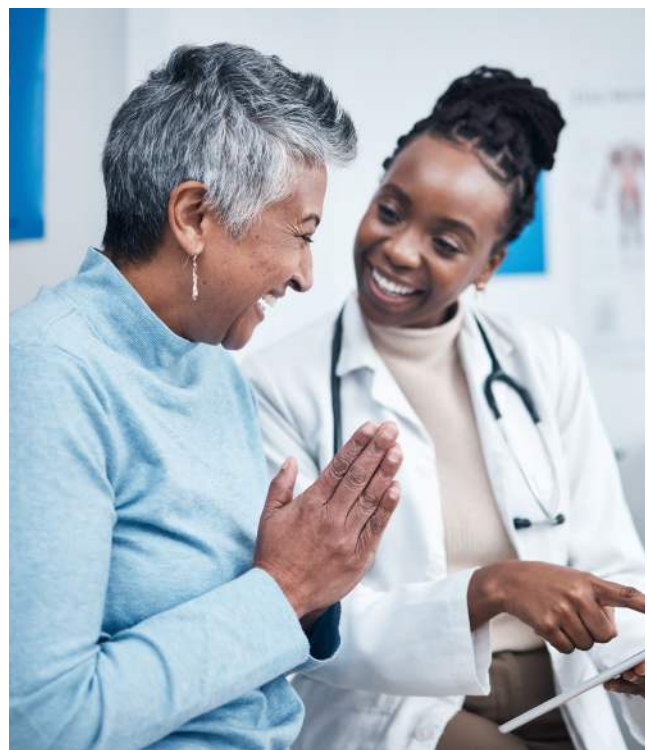
Care coordination is another important component of value-based health care. A study published in the *Journal of General Internal Medicine* found that care coordination interventions reduced hospital admissions by 17% and emergency department visits by 7%.<sup>3</sup> By ensuring that patients receive appropriate and timely care across different health care settings, value-based models can improve patient outcomes and reduce unnecessary health care utilization.

### Patient Engagement

Value-based models prioritize and encourage patient involvement in decision-making, self-management, and adherence to treatment plans. By actively engaging patients in their own care, health care providers can foster a collaborative and empowering environment that leads to improved health outcomes and reduced health care utilization.

#### Sources:

1. "Value-Based Health Care Initiatives in Practice: A systemic Review," National Library of Medicine, accessed January 17, 2024, <https://pubmed.ncbi.nlm.nih.gov/31098976/>
2. "Value based care growth stagnant in 2022," Health Care Payment Learning and Action Network, accessed January 17, 2024, <https://hcp-lan.org/2023/12/value-based-care-growth-stagnant-in-2022/>
3. "Health Care Coordination Theoretical Frameworks: A Systematic Scoping Review to Increase Their Understanding and Use in Practice," National Library of Medicine, accessed January 17, 2024, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8423138/content=newsletter&oly\\_enc\\_id=891815416778F9M](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8423138/content=newsletter&oly_enc_id=891815416778F9M)



# Pharmacy 101

## Limited Distribution Drugs

Limited distribution drugs (LDDs) are medications that are subject to strict distribution controls due to various factors, such as safety concerns, limited availability, or high cost.

These drugs are typically used to treat complex or rare medical conditions and require specialized handling, monitoring, and administration. LDDs have an average annual cost of \$78,000.<sup>1</sup>

### Distribution & Special Handling

The distribution of LDDs is tightly regulated to ensure that these medications are used appropriately and reach the patients who need them the most. Pharmaceutical manufacturers often establish restricted distribution networks or specialty pharmacies to manage the supply chain and ensure the proper handling and dispensing of LDDs. These medications also require “special supply chain tools, ranging from inventory management to cold chain delivery to REMS (risk evaluation and mitigation strategies) programs.”<sup>2</sup>

LDDs may necessitate specific storage conditions, such as refrigeration or protection from light, to preserve their stability and effectiveness. Furthermore, certain LDDs may entail complex dosing regimens or necessitate specialized training for administration. As a result, it becomes imperative to limit their distribution to health care professionals who possess the necessary expertise and qualifications.

### Patient Safety

Some LDDs may carry a higher risk of adverse effects or require close patient monitoring due to their potential for serious side effects. By restricting distribution, manufacturers can ensure that health care providers are aware of the necessary precautions and can closely monitor patients who are prescribed these medications.



### Small Patient Populations

Limited distribution drugs are frequently utilized to treat rare diseases or conditions that impact a small population. Drugs targeting orphan diseases, for example, affect fewer than 200,000 individuals.<sup>3</sup> These medications may represent the sole treatment options available for these patients, underscoring the importance of guaranteeing their appropriate distribution and accessibility. The small distribution models enable manufacturers to gather and analyze data on prescribers, patient adherence, and discontinuation rates, thereby facilitating the tracking of clinical outcomes and ensuring appropriate oversight and monitoring.

#### Sources:

1. “Average annual price of specialty drugs has nearly tripled since 2006 study finds,” Becker’s Hospital Review, accessed January 16, 2024, <https://www.beckershospitalreview.com/pharmacy/average-annual-price-of-specialty-drugs-has-nearly-tripled-since-2006-study-finds.html>
2. “Limited Distribution Drugs: What You May Not Know,” Navitus, accessed January 16, 2024, <https://blog.navitus.com/limited-distribution-drugs-0>
3. “What Makes a Drug Special?,” AMCP, accessed January 16, 2024, <https://www.amcp.org/Resource-Center/specialty-pharmacy/what-makes-drug-special-defining-specialty-medications>

# Disease Spotlight

## Understanding RSV

Respiratory syncytial virus (RSV) is a common seasonal virus that primarily affects children.

RSV, which stands for Respiratory Syncytial Virus, is a primary contributor to respiratory infections in infants. This virus is responsible for around 58,000 hospitalizations among children under the age of five every year.<sup>1</sup> In older adults and individuals with weakened immune systems, it can also lead to severe illness, resulting in approximately 14,000 deaths each year in adults over age 65.<sup>1</sup> RSV is highly contagious and spreads through respiratory droplets when an infected person coughs or sneezes.

### Etiology

RSV infections typically occur during the fall, winter, and early spring months. The virus can cause a range of symptoms, from mild cold-like symptoms to more severe respiratory infections. In healthy individuals, RSV may present as a common cold with symptoms such as a cough, runny nose, sneezing, and fever. However, in infants and individuals with compromised immune systems, RSV can lead to more serious complications.

One of the most common complications of RSV infection in infants is bronchiolitis, which is an inflammation of the small airways in the lungs.<sup>2</sup> Bronchiolitis can cause difficulty breathing, wheezing, and a persistent cough. In severe cases, RSV can lead to pneumonia, especially in vulnerable populations.

### Susceptible Populations

Infants under the age of one are particularly susceptible to severe RSV infections. Premature infants, infants with congenital heart or lung diseases, and those with weakened immune systems are at a higher risk of developing severe symptoms. Older adults, especially those with underlying health conditions, are also more susceptible to severe RSV infections.



### RSV Treatments

There is no specific treatment for RSV, and most cases can be managed with supportive care. Two types of preventative treatments are available today: monoclonal antibody immunizations and vaccines.

1. Monoclonal antibody immunizations are given to high-risk infants and children in the first 24 months after birth to help reduce the risk of RSV-related hospitalizations. Currently, there are two products on the market: Synagis and Beyfortus.
2. Two newer vaccines, Abrysvo and Arexvy, have been launched to prevent lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older. Abrysvo also has the additional use in pregnant individuals at 32 through 36 weeks gestational age to prevent RSV in infants from birth through six months of age.<sup>3</sup>

#### Sources:

1. "Respiratory Syncytial Virus (RSV)," National Institute of Allergy and Infectious Disease, accessed December 7, 2023, <https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv>
2. "Respiratory Syncytial Virus (RSV)," Mayo Clinic, accessed December 7, 2023, <https://www.mayoclinic.org/diseases-conditions/respiratory-syncytial-virus/symptoms-causes/syc-20353098>
3. "Abrysvo™ prescribing information, Pfizer Pharmaceuticals," accessed December 6, 2023, <https://abrysvoadult.pfizerpro.com/>.



# Clinical Spotlight

## Chimeric Antigen Receptor T-cell (CAR-T) therapy

CAR-T therapy is a groundbreaking form of immunotherapy that has revolutionized the treatment of certain types of cancer.

It involves genetically modifying a patient's own T-cells to recognize and attack cancer cells in the body. Since 2017, the Food & Drug Administration (FDA) has approved six CAR-T therapies. These therapies have been approved for the treatment of blood cancers, such as lymphomas, certain types of leukemia, and most recently, multiple myeloma.<sup>1</sup>

### Process

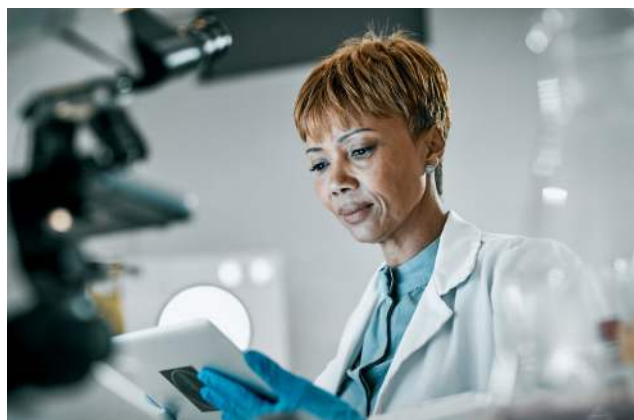
The process of CAR-T therapy begins with the collection of a patient's T-cells through a process called leukapheresis. These T-cells are then sent to a laboratory where they are genetically engineered to express a chimeric antigen receptor (CAR) on their surface, which will recognize a specific antigen present on the surface of cancer cells. The cells are then grown and multiplied in the lab in a process that can take several weeks to produce the large number of CAR-T cells needed.<sup>2</sup>

Once collected, these cells are then infused back into the patient, where they can recognize and target cancer cells that express the antigen recognized by the CAR. The CAR-T cells undergo a rapid expansion in the patient's body, leading to a sustained anti-cancer immune response.

### Side Effects

Despite their success, CAR-T therapies are associated with unique challenges and potential side effects. The activation of CAR-T cells can lead to a phenomenon called cytokine release syndrome (CRS), which is characterized by the release of inflammatory cytokines and can cause flu-like symptoms, fever, and in severe cases, organ dysfunction. Another potential side effect is neurotoxicity, which can manifest as confusion, seizures, and other neurological symptoms.

To manage these side effects, specialized medical teams closely monitor patients receiving CAR-T therapy and provide supportive care, including the administration



of immunosuppressive drugs and other interventions. Ongoing research is focused on improving the safety and efficacy of CAR-T therapies, including the development of next-generation CAR designs and combination therapies.

### Costs and Outcomes

Prior to the development of CAR-T therapy, the standard treatment for these types of cancers was a stem cell transplant (SCT) with a corresponding inpatient hospital stay associated with both pharmacy and medical costs. Due to the nature of CAR-T therapy, inpatient hospital stays are also required to administer the drug and to monitor the patient for side effects and efficacy, however, according to one study, the mean length of stay was between 3-10 days shorter while receiving CAR-T as compared to those undergoing a SCT.<sup>3</sup> These lower non-pharmacy charges were tempered by higher upfront pharmacy charges associated with CAR-T therapy, where charges could be as high as \$450,000.<sup>3</sup> This study found slightly higher overall costs for CAR-T therapy, but also found benefits which included shorter ICU stays and lower ICU admission rates.<sup>3</sup>

CAR-T therapy has shown remarkable efficacy in clinical trials, with high response rates and durable remissions observed in patients with relapsed or refractory hematological malignancies. Ongoing research is exploring CAR-T's potential for treatment of other types of cancer.

### Sources:

1. "CAR T Cells: Engineering Patients' Immune Cells to Treat Their Cancers," National Cancer Institute, accessed December 11, 2023, <https://www.cancer.gov/about-cancer/treatment/research/car-t-cells>.
2. "CAR T Cell Therapy and Its Side Effects," American Cancer Society, accessed December 11, 2023, <https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/car-t-cell1.html>.
3. "CAR T-Cell Therapy Leads to Shorter Hospital Stays, Lower Nonpharmacy Costs Despite High Overall Cost," OneLive, accessed December 11, 2023, <https://www.onlive.com/view/car-t-cell-therapy-leads-to-shorter-hospital-stays-lower-nonpharmacy-costs-despite-high-overall-cost>.

# Pipeline

## Pending drug approvals

Drug name	Manufacturer	Indication/use	Expected FDA decision date
eculizumab (biosimilar to Alexion's Soliris)	Amgen	PNH; Hemolytic uremic syndrome	February 2024
lifleucel	Iovance	Melanoma	2/24/2024
roluperidone	Minerva	Schizophrenia	2/26/2024
Resmetirom	Madrigal	NASH (liver fibrosis)	3/14/2024
atidarsagene autotemcel	Orchard	Metachromatic leukodystrophy	3/18/2024
Sotatercept	Merck		3/26/2024
exagamglogene autotemcel	Vertex/CRISPR	Beta-thalassemia (transfusion-dependent)	3/30/2024
insulin lispro (biosimilar to Eli Lilly's Humalog)	Gan & Lee/Sandoz	T1DM; T2DM	4/01/2024
apomorphine infusion device	Supernus	Parkinson's disease	4/09/2024
insulin aspart (biosimilar to Novo Nordisk's Novolog)	Gan & Lee/Sandoz	T1DM; T2DM	4/14/2024
ranibizumab (biosimilar to Genentech's Lucentis)	STADA Arzneimittel/ Xbrane	Diabetic retinopathy; DME; Myopic choroidal neovascularization; Macular edema following RVO; Wet AMD	4/21/2024
rituximab (biosimilar to Genentech's Rituxan)	Dr. Reddy's	CCL; Granulomatosis; NHL; Mature B-cell NHL/mature B-cell acute leukemia; Pemphigus vulgaris; RA	5/10/2024

## Brands Losing Patent

Drug name	Manufacturer	Indication/use	Expected FDA decision date
Complera	Emtricitabine, Rilpivirine, Tenofovir	HIV	January 2024
Gralise	Gabapentin	Neuropathic pain	January 2024
Omidria	Ketorolac 0.3%/ Phenylephrine 1%	Used during eye surgery & to lower eye pain after eye surgery	January 2024
Exparel	bupivacaine	Post-operative pain management	March 2024
Farxiga	dapagliflozin	Diabetes, heart disease, kidney disease	April 2024
Ionsys	fentanyl hydrochloride	Pain management	April 2024
Contrave	bupropion hydrochloride; naltrexone hydrochloride	Weight management	April 2024
Entresto	sacubitril and valsartan	Chronic heart failure	May 2024
Xarelto	rivaroxaban	Prevent blood clots	August 2024

\*Actual launch dates depend on FDA approvals and may change at any

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