ADVANCES IN CANCER TREATMENT WITH CAR T CELLS

In a time when many new, innovative medications and therapies are gaining approval from the Food and Drug Administration (FDA), it's critical to understand these remedies, determine the right situations to seek them out, and discern the financial impact they may have in associated claim costs.

At AXIS Re, we help clients manage the cost and quality of care with our substantive claims expertise. Our network of preferred specialty vendors and service providers evaluates the effectiveness of treatments and assists us in identifying clinical facilities with a track record of positive outcomes. We assist our clients with analyzing treatment options and costs, so that quality care can be delivered in the most cost-effective way.

What is CAR T-cell therapy?

Chimeric Antigen Receptor (CAR) T-cell therapy is a type of immunotherapy for cancer treatment called Adoptive Cell Transfer, or "ACT." In ACT, the patient's own immune cells are reprogrammed to fight cancers in smarter, targeted ways. While there are several types of ACTs being actively researched and tested, CAR T-cell therapy is the only treatment approved for use by the FDA in the United States.[1]

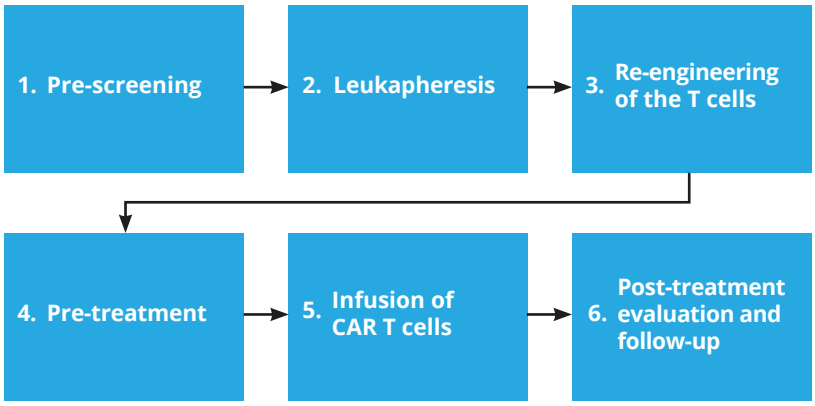
What are the FDA-approved therapies?

As of November 30, 2018, there are only two FDA-approved CAR T-cell therapies in the United States: **Kymriah**, also known as Tisagenlecleucel, manufactured by Novartis, and **Yescarta**, also known as Axicabtagene Ciloleucel, manufactured by Kite Pharma, Inc.

These drugs have very specific applications that require careful screening and placement of the patient. Each manufacturer has worked with a very limited number of facilities to certify them for administration of the protocols associated with this type of therapy.

What is a typical course of treatment?

The process starts with the very careful pre-screening of a candidate and progresses through post-procedure care, reaction management, and continuous follow-up for several years. The treatment process can be broken out as follows:



What are the potential side effects?

No pharmacological treatment is without side effects. CAR T-cell therapy is a new treatment that has only just been made available. A number of side effects have been reported in the clinical trials and new studies are underway on the broader patient population. These side effects range from mild symptoms, such as fever and chills, to very complex conditions, including seizures, which require critical care.

Potentially costly side effects include:

- **Cytokine Release Syndrome** – a systemic inflammatory response causing great discomfort
- **Neurotoxicity** – confusion, delirium, difficulty speaking, and inflammation of the brain/seizure activity
- **B cell Aplasia** – the treatment may destroy nonmalignant B cells that results in a lack of antibodies to fight other organisms

References

[1] NIH National Cancer Institute. CAR T cells: engineering patients' immune cells to treat their cancers. Accessed 3 September 2018. https://www.cancer.gov/about-cancer/treatment/research/car-t-cells

[2] **Conservative Estimate:** Presumes minimal complications and optimal conditions for infusion.

Moderate Estimate: Presumes a higher level of complications requiring treatment with short inpatient stay, possible anti-inflammatory drugs, and/or limited treatment with an immunoglobulin.

High Estimate: Presumes severe adverse reactions resulting in prolonged inpatient ICU stay with neurotoxicity and severe CRS.

What is the overall cost of treatment?

CAR T-cell therapy will cost no less than $500K, but will likely be closer to $1M, depending on patient side effects.

CAR T-cell Therapy Treatment Costs

To give insurers a better sense of potential costs, we grouped various reported gross billed charges into three levels of care related to a course of CAR T-cell treatment.

CAR T-CELL THERAPY	COST ESTIMATE[2]		
	No complications	Short-term complications	Severe complications
Pre-treatment screening	$500	$500	$500
Leukapheresis, freezing T cells and shipping	$7,500	$7,500	$7,500
Drug cost and T cell cultivation • Yescarta • Kymirah	 $400,000 $500,000	 $400,000 $500,000	 $400,000 $500,000
T cell infusion and inpatient stay	1–3 day inpatient stay regular room $6,000	ICU < 5 days Regular room ≤ 21 days $700,000	Prolonged ICU care Anti-inflammatory and anti-seizure treatment $2,000,000
Follow-up monitoring • 6 months to 1 year	$1,200	$1,200	$1,200
Estimated Total Gross Billed Charges • Yescarta • Kymirah	 **$415,200** **$515,200**	 **$1,109,200** **$1,209,200**	 **$2,409,200** **$2,509,200**

How can AXIS Re help?

Effective screening of patients and selection of a properly authorized facility are critical to the success of CAR T-cell therapy. AXIS Re can support you throughout the entire process. For more information on this or any other new therapy, please reach out to your contact at AXIS Re or email AccidentReClaimsNAM@axiscapital.com

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