

Pharmacy Focus: 2018 Cancer Therapy Update



CART-Cell Therapy Overview

The American Society of Clinical Oncology (ASCO) named adoptive cell immunotherapy as the Advance of the Year. Does this mean a cure has been found? The short answer is no – while medicine has made amazing strides in understanding and approaching cancer, there is still a lot of work to be done.

One type of immunotherapy is CART-cell therapy. According to the National Cancer Institute, CART-cell therapy is a treatment in which a patient's T-cells (immune system cells) are changed in a laboratory to attack cancer cells. T-cells are first removed from a patient's blood. Then, in a laboratory, the gene for a special receptor that binds to a certain protein on the patient's cancer cells is added. The special receptor is called a chimeric antigen receptor (CAR). Large numbers of these CAR T-cells are then grown in the laboratory. Finally, they are returned to the patient by infusion.¹ The therapy has both potential benefits and adverse effects that can impact patient outcomes.

Two FDA-approved CART T-cell therapies are Kymriah™, which is designed for the treatment of those to age 25 with advanced acute lymphoblastic leukemia (ALL), and Yescarta™, which is for adults with advanced lymphomas.

Drug	Therapy ICD-10 Code	Commonly Used Disease	Disease ICD-10 Code
Kymriah™ (tisagenlecleucel)	Q2040	Acute Lymphoblastic Leukemia (ALL)	C91
Yescarta™ (axicabtagene)	Q2041 (effective 4/18)	Non-Hodgkin Lymphoma	C85

Business Considerations

- Clarify plan language to address value-based (outcomes-based) payment models
 - Claims for Kymriah™ should be expected after the clinical guarantee is fulfilled
- Know your population risk (cross-reference approved diagnoses with billable ICD-10 codes)
- Define therapy limitations
 - One-time use with defined eligibility criteria
 - In-network vs. out-of-network authorized treatment center and the most cost-effective options
 - Carve-out “off-label”/non-FDA approved uses, including:
 - Repeat attempts **after** first infusion
 - Maintenance therapy or bridge therapy awaiting a stem cell donor
 - Administering prematurely (without required completion of Best Practices, including requirement of two years of chemotherapy with disease progression)
- Prepare for potential expenditures **after** therapy, including stem cell transplantation and/or more chemotherapy

CAR T-cell therapy expenses may cost up to \$1.5 million per therapy*

Direct Costs Include:

- Must be provided at an authorized treatment center
- 7-14 day hospitalization
- Harvesting patient cells via leukapheresis
- Chemotherapy pretreatment
- Actemra® x2 to minimize serious side effects
- Immune globulin therapy
- Housing within a 2-hour drive for 4 weeks

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Clinical Therapy Considerations

	Yescarta™² (Axicabtagene)	Kymriah™³ (Tisagenlecleucel)
FDA Approved Use	Adult patients with specific relapsed or refractory non-Hodgkin Lymphoma (NHL), called large B-cell lymphoma after two or more lines of systemic therapy Types of NHL include: <ul style="list-style-type: none"> • Diffuse large B-cell lymphoma (DLBCL) NOS • Primary mediastinal large B-cell lymphoma • High grade B-cell lymphoma • DLBCL arising from follicular lymphoma 	Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse
Population	Approximately 7,500 American adults per year	Approximately 750 American children per year ⁴
FDA Approved Dosing	68mL of viable cell therapy	Max 50mL of viable cells
Direct Costs	<ul style="list-style-type: none"> • Must be provided at an authorized treatment center • 7-14 day hospitalization • Harvesting patient cells via leukapheresis • Chemotherapy pretreatment • Actemra® x 2 to minimize serious side effects • Immune globulin therapy • Housing within a 2-hour drive for 4 weeks 	<ul style="list-style-type: none"> • Must be provided at an authorized treatment center • 7-14 day hospitalization • Harvesting patient cells via leukapheresis • Chemotherapy pretreatment • Actemra® x 2 to minimize serious side effects • Immune globulin therapy • Housing within a 2-hour drive for 4 weeks
Adverse Effects	<ul style="list-style-type: none"> • Prolonged ICU/hospitalization stay • Permanent disability • Death 	<ul style="list-style-type: none"> • Prolonged ICU/hospitalization stay • Permanent disability • Death
Study Information	101 lives (very small study) <ul style="list-style-type: none"> • 72% of patients in complete/partial remission • Median response time was 0.9 months • Duration of response/effect measured up to 9.2 months 	68 lives (very small study) <ul style="list-style-type: none"> • 82.5% patients in remission within 3 months • Median response time was 29 days • Duration of response measured beyond 14.1 months
Payment Structures	Traditional	Outcomes-Based / Value-Based
Traditional Therapies	In any combination: <ul style="list-style-type: none"> • Multi-drug chemotherapy • Stem cell transplant • Radiation therapy • Monoclonal antibodies (Rituxan®, Gazyva®, Zevalin®) 	In any combination: <ul style="list-style-type: none"> • Multi-drug chemotherapy • Stem cell transplant • Monoclonal antibodies
After Treatment	<ul style="list-style-type: none"> • Additional (off-label) Yescarta™ • Defer to traditional therapies 	<ul style="list-style-type: none"> • Off-label use of Kymriah™ • Defer to traditional therapies

NOTE: Ongoing study evaluating the effect of Kymriah™ on adults with NHL has been promising. If Kymriah™ receives additional FDA approval for adults with NHL, there would be an opportunity for competitive pricing, including outcomes-based pricing.⁵

Pharmacy Focus provides valuable information about pharmaceutical industry developments and their associated costs that can impact the growing claims trend in the self-funded insurance market. Be aware of influences and gain insight into approaches that may help to contain costs. Please share topic suggestions or feedback with HMPHarmacyServices@hmig.com.

^{*}Cost is estimated based on average charges for direct services/treatments used alongside the drug.

References: ¹ "CAR T-Cell Therapy," NCI Dictionary of Cancer Terms, National Cancer Institute, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy>, accessed April 4, 2018; ²Yescarta [prescriber information]. Kite Pharm Inc., Santa Monica, CA, October 2017; ³Kymriah [prescriber information]. Novartis Pharmaceuticals Corporation, East Hanover, NJ, August 2017; ⁴Hirawat S. CTL019 (tisagenlecleucel) in pediatric and young adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia, presented for Novartis at: USFDA Oncology Advisory Committee, July 12, 2017; ⁵Schuster SJ, Bishop MR, Tam CS, et al., Primary analysis of JULIET: A global, pivotal, phase 2 trial of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma, presented at: ASH Annual Meeting and Exposition, December 9-12, 2017, Atlanta, Abstract 577

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