

EMERGING THERAPY SOLUTIONS® THERAPY OVERVIEW



Emerging Therapy Solutions and LifeTrac came together to offer a complete solution for managing risk associated with rare and complex medical conditions and high dollar treatments. LifeTrac's extensive experience in bone marrow and solid organ transplants provides an excellent complement to Emerging Therapy Solutions' expertise in cell and gene therapies.



Forecasting

We monitor the U.S. clinical trial pipeline to determine which cell and gene therapies are coming and when. We leverage a claims database of over 90 million lives to simulate your population, estimating how many people may be eligible to receive these high-cost treatments.



Expert Content

We curate content that is not readily available. Our extensive clinical education resources include condition- and therapy-specific webinars and overviews, curated news, quarterly pipeline reports, and medical policy guidance and language for newly approved and coming cell and gene therapies.



Physician Review

If a further review is needed on any patient or insured proposed treatment plan, we offer single or multiple external reviews by leading physicians in each respective condition. Along with our policy and medical background information, these reviews can help you determine if a requested therapy is appropriate.

Learn more at
emergingtherapies.com
lifetracnetwork.com
or call 877.445.4822

What is Abecma (idecabtagene vicleucel)?

Abecma, previously called ide-cel, is a cell therapy from Bristol Myers Squibb and bluebird bio. Abecma is approved for adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Abecma is a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T-cell (CAR-T) therapy. Learn more at: [BMS Package Insert](#)

What is multiple myeloma?

Multiple myeloma is a cancer that begins in plasma cells. It is characterized by a growth of malignant plasma cells primarily in the bone marrow. Plasma cells are a type of white blood cell that makes antibodies which help fight infection. These malignant cells can crowd out normal blood cells in the bone marrow, destroy the bone matrix and spread to other areas of the body. Multiple myeloma is highly treatable but rarely curable. The cause of multiple myeloma has not been established but risk factors include age, gender, ethnicity, genetic mutations, environmental and occupational exposures, radiation exposure and infections. Multiple myeloma may produce a wide variety of symptoms, but bone pain in the spine is typically the initial presenting symptom.

What is CAR-T therapy?

CAR-T stands for chimeric antigen receptor T-cell. This is a type of immunotherapy through which a cancer patient's own immune cells are collected, modified and used to treat their cancer. T-cells are a type of white blood cell which protect the body from infection. Once the patient has been screened and deemed eligible for CAR-T therapy, the treatment process includes:

- **Leukapheresis** – T-cells are removed from the patient and shipped to the manufacturer.
- **Cell manufacturing** – The manufacturer genetically engineers the CAR-T cell.
- **Conditioning chemotherapy** – Prepares the body for treatment.
- **Infusion** – CAR-T cells are infused back into the patient (a one-time infusion).
- **Monitoring** – Patient remains inpatient until side effects are under control, then remains within two hours of the treatment facility for four weeks.

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Programs of Excellence

Our programs of excellence model identifies clinics and hospitals that deliver quality, cost-effective care. We focus on programs with proven performance that evaluate a variety of treatment options and consider the patient's entire condition.



Referral Support

When a patient is referred for a cell or gene therapy, transplant, or other specialty treatment, we support the process and have the expertise to review and reprice claims, focusing on claims accuracy.

References

- <https://endpts.com/bristol-myers-squibb-lands-once-high-stakes-approval-on-bcma-car-t-jj-is-breathing-down-its-neck/>
- ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells Lee, Daniel W, et al. Biology of Blood and Bone Marrow Transplantation, Volume 25, Issue 4, 625-63
- Press Release: U.S. Food and Drug Administration Approves Bristol Myers Squibb's and bluebird bio's Abecma (idecabtagene vicleucel), the first Anti-BCMA CAR T Cell Therapy for Relapsed or Refractory Multiple Myeloma, <https://news.bms.com/news/details/2021/U.S.-Food-and-Drug-Administration-Approves-Bristol-Myers-Squibbs-and-bluebird-bios-Abecma-idecabtagene-vicleucel-the-First-Anti-BCMA-CAR-T-Cell-Therapy-for-Relapsed-or-Refractory-Multiple-Myeloma/default.aspx>
- <https://www.businesswire.com/news/home/20210326005507/en/U.S.-Food-and-Drug-Administration-Approves-Bristol-Myers-Squibb%E2%80%99s-and-bluebird-bio%E2%80%99s-Abecma-idecabtagene-vicleucel-the-First-Anti-BCMA-CAR-T-Cell-Therapy-for-Relapsed-or-Refractory-Multiple-Myeloma>
- https://www.fda.gov/media/147055/download?utm_medium=email&utm_source=govdelivery
- National Comprehensive Cancer Network (NCCN) Guidelines for Patients® Multiple Myeloma 2019. www.NCCN.org

What is the current course of treatment?

Current treatment depends upon the person's age, stage of their cancer, and health of the patient. Treatment options include chemotherapy, stem cell transplants, surgery, radiation or a combination of these options. The National Comprehensive Cancer Network (NCCN) provides information on the sequencing of treatment options. Participation in a clinical trial is another treatment option for patients to consider.

What are the potential side effects?

This therapy, like other CAR-T therapies, has a Boxed WARNING (U.S. Food and Drug Administration warning) regarding cytokine release syndrome (CRS) and neurologic toxicities (NT), that can each be serious and potentially life-threatening, requiring longer inpatient stays and ICU management:

Cytokine release syndrome (CRS) - A systemic inflammatory response caused by a large rapid release of cytokines into the blood stream from the infused T-cells. Signs and symptoms include fever, nausea, headache, rash, rapid heartbeat, low blood pressure and trouble breathing.

Neurotoxicity - The pathophysiology of neurotoxicity related to CAR-T therapy is not yet known. Signs and symptoms include confusion, headache, delirium, seizures, and language disturbance.

What is the current estimated cost for treating a patient?

Abecma has a list price of \$419,500.

How does this impact my business?

The decision for which CAR-T to use is an important component of the patient evaluation, along with having members evaluated at experienced Programs of Excellence. To submit a referral or to learn about our CAR-T Program of Excellence model, please contact us at medicalservices@emergingtherapies.com or call 877.445.4822.