

Premium

India's own CAR-T cell therapy: What is it, when will it be available, and at what cost?

The drugs regulator has granted market authorisation to India's breakthrough CAR-T cell therapy for patients with B-cell lymphomas who didn't respond to standard treatments like chemotherapy.

Written by Rahul Purwar
New Delhi | Updated: November 2, 2023 08:27 IST



PREMIUM

EXPRESS explained HEALTH

EXPRESS EXPLAIN

Hamas: Its c the role Israe strengthenin

AD Plumbing Jobs Might Be Easier to Get Than...

AD Healthcare Courses Might be More in...

CAR-T is a revolutionary therapy that modifies immune cells, specifically T-cells, by turning them into potent cancer fighters known as CAR-T cells.

Listen to this article

00:00 1x 1.5x 1.8x

The Central Drugs Standard Control Organisation (CDSCO) this month granted market authorisation for NexCAR19, India's first indigenously-developed **CAR-T cell therapy**, to ImmunoACT, a company incubated by IIT Bombay. This paves the way for the commercial launch of this therapy in India, where it is expected to be available to cancer patients at a tenth of the cost abroad.

What is CAR-T cell therapy, and how do CAR-T cells find and destroy cancer cells?

CAR-T is a revolutionary therapy that modifies immune cells, specifically T-cells, by **turning them into potent cancer fighters** known as CAR-T cells. T-cells are special cells (white blood cells that find and fight illness and infection) whose primary function is cytotoxic, meaning it can kill other cells. In CAR-T therapy, we genetically modify them into **cancer-fighting cells**. These supercharged cells are then put back into the body, and they go after cancer cells — especially in blood cancers like leukaemia and lymphomas.

EXPRESS EXPLAIN



**Hamas: Its c
the role Israe
strengthenin**

TREATMENT FOR SPECIFIC B-CELL CANCERS

NexCAR19 is a prescription drug for B-cell lymphomas, lymphoblastic leukaemias when other treatments have been unsuccessful

PATIENT'S WHITE blood cells are extracted by a machine through a process called leukapheresis and genetically modified, equipping them with the tools to identify and destroy the cancer cells.



NEXCAR19 IS manufactured to an optimal dose for the patient, and typically administered as a single intravenous infusion. Prior to this, the patient is put through chemotherapy to prime the body for the therapy.

HOW NEXCAR19 WORKS



T-cells are naturally made by the body as an advanced defence against viruses and cancer cells.

As T-cells mature, they develop specific connectors (receptors) to target key signals on cancer cells.



However, cancers can limit the inbuilt extent and efficiency with which T-cells are able to seek and fight them. This results in an increase in cancer burden.

Source: ImmunoACT



Scientists have identified certain proteins that are abnormally expressed on the surfaces of specific types of cancer cells. Specially designed receptors can find and bind to these cells.



A safe shell of a virus is used to genetically engineer T-cells so they express Chimeric Antigen Receptors – connectors that target a protein called CD19 on B-cell cancer.

How effective and different is this from other cancer treatments like, say, chemotherapy?

While chemotherapy and immunotherapy may add a few months or years to a **cancer patient's life**, cell-and-gene therapy is designed to cure and provide lifelong benefit. It makes treatment easier with a one-time therapy [unlike several sessions of chemotherapy] that can be truly transformative [for a patient]. It's a lifeline for non-responsive cancer patients.

Is NexCAR19 a type of CAR-T therapy?

NexCar19 is a type of CAR-T and gene therapy developed indigenously in India by ImmunoACT, which is a company incubated at IIT Bombay. Our therapy is designed to target cancer cells that carry the CD19 protein. This protein acts like a flag on

cancer cells, which allows CAR-T cells to recognise and attach themselves to the cancer cells and start the process of elimination.

Even some developed nations don't have their own CAR-T therapies; they import them from the United States or Europe. India is now one of the first developing countries to have its indigenous CAR-T and gene therapy platform.

EXPRESS EXPLAIN



Hamas: Its role in the conflict with Israel is strengthening

Who can get the NexCAR19 therapy?

The therapy is for people with B-cell lymphomas who didn't respond to standard treatments like chemotherapy, leading to relapse or recurrence of the cancer.

The patient's journey starts with a doctor's prescription at the clinic, followed by donation of blood by the patient at a transfusion centre. The blood goes to the lab, where the T-cells are genetically modified. In a week to 10 days, these cells return to the clinic for patient reinfusion. Essentially, patients only need to give a blood sample at their clinic, and come back in 7-10 days for reinfusion.

Recovery typically occurs within two weeks after one cycle of the treatment. In our data, approximately 70% of patients respond to the treatment, with variations between leukaemia and lymphoma cases. About 50% of these responsive patients achieve a complete response.

B-cell leukaemia is most common among children. Are they eligible for the therapy too?

The paediatric trial phase is currently underway at the Tata Memorial Hospital, in collaboration with IIT-Bombay. Although the therapy for children will not be any different, for now, ImmunoACT has received CDSCO approval for use in patients aged 15 years and older.

Is India's indigenous CAR-T cell therapy any more or less effective than CAR-T cell therapies abroad?

Laboratory and animal studies have shown a unique quality of this product. Specifically, it leads to significantly lower drug-related toxicities. It causes minimal damage to neurons and the central nervous system, a condition known as

neurotoxicity. Neurotoxicity can sometimes occur when CAR-T cells recognise the CD19 protein and enter the brain, potentially leading to life-threatening situations.

The therapy also results in minimal Cytokine Release Syndrome (CRS), which is characterised by inflammation and hyperinflammation in the body due to the death of a significant number of tumour cells, as CAR-T cells are designed to kill and eliminate cancer cells. You can think of this like how the body responds to a virus such as SARS-CoV-2, where the immune response triggers an influx of certain proteins called cytokines, causing a lot of inflammation.

EXPRESS EXPLAIN



**Hamas: Its c
the role Israe
strengthenin**

ALSO READ | The next big advance in cancer treatment could be a vaccine

When will this therapy be available to patients in India?

We are in the process of obtaining licenses and onboarding hospitals. Tata Hospital is our preferred partner, and we've also got other hospitals like Nanavati, Fortis, and Jaslok in [Mumbai](#) on board. We have also added multiple hospitals in cities like [Hyderabad](#), [Pune](#), and [Delhi](#).

The timeline for them to start offering CAR-T therapy may be a matter of weeks to a few months, contingent on final government approvals. Some minor approvals, including the manufacturing licence from the state government and approval of the label and pack insert by the Drugs Controller General of India, are still pending. Once these are secured, we aim to make CAR-T therapy accessible to everyone within a short timeframe.

ALSO READ | These cutting-edge technologies have revolutionised cancer care in India

How much will this treatment cost?

Currently, we are looking at a price range of Rs 30-40 lakh for CAR-T therapy, which we intend to hold. Even at this cost, it may not be accessible to everyone. Our ultimate goal is to bring the cost down to Rs 10-20 lakh. As technology matures and manufacturing processes improve, we anticipate that the cost will decrease. We're committed to making this therapy accessible to as many people as possible.

Will the treatment be covered by insurance?

When a therapy is approved by regulatory agencies like CDSCO or DCGI, it should be covered by national insurance schemes and private insurance companies. However, since this is an expensive treatment, the extent of coverage and accessibility to insurance may vary. We will engage in discussions with insurers and the government to clarify this further.

EXPRESS EXPLAIN



**Hamas: Its c
the role Israe
strengthenin**

ALSO READ



Why Yemeni Houthis' attack on Israel has many worried



Why GST collections surged sharply in October



Hamas: Its conflict with Fatah, and the role Israel played in strengtheni...



Why IDBI Bank has taken Mumbai Metro One to bankruptcy court

Dr Purwar is associate professor in the Department of Biosciences and Bioengineering at IIT Bombay and CEO of ImmunoACT. He spoke to Rupsa Chakraborty and Ritika Chopra.

© The Indian Express Pvt Ltd

First published on: 02-11-2023 at 07:07 IST

TAGS: Central Drugs Standard Control Organisation Express Premium

ADVERTISEMENT