

Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia

What does the guidance say?

Tisagenlecleucel is recommended for inclusion on the MOH Cell, Tissue and Gene Therapy Product (CTGTP) List for government funding for patients with relapsed or refractory B-cell acute lymphoblastic leukaemia who meet certain clinical criteria.

What is acute lymphoblastic leukaemia?

Acute lymphoblastic leukaemia (ALL, also called acute lymphocytic leukaemia) is a fastgrowing cancer that affects the blood and bone marrow and causes white blood cells to grow uncontrollably and produce "leukaemia cells". As the number of leukaemia cells increases, there is less room for healthy blood cells, making patients more susceptible to anaemia (lack of red blood cells) and infections. Doctors classify ALL into different subtypes depending on the type of blood cells that are affected.

When leukaemia cells grow instead of B-cell lymphocytes, this is known as B-cell ALL. This is the most common subtype of ALL in children and adults. Early symptoms may include bleeding from the gums, bone pain, fever, frequent infections, pale skin, weakness and shortness of breath.

Many patients with B-cell ALL achieve remission (that is, when the cancer is gone or no longer requires treatment) with chemotherapy. However, sometimes the cancer can come back after treatment (relapsed) or continues to worsen (refractory), and a different treatment will be given. Some patients with B-cell ALL may be able to have a stem cell transplant (haematopoietic cell transplant), where stem cells are removed from the patient's or donor's blood and then later put into the patient's body after high doses of chemotherapy are given. This helps to restore the bone marrow and rebuild the immune system.

Doctors determine which treatment is likely to work best by considering the age of the patient and their general health, as well as which treatments have been tried before.

What is tisagenlecleucel?

Tisagenlecleucel is a type of immunotherapy called chimeric antigen receptor T-cell therapy (CAR-T). It is a one-time treatment that includes different steps over several weeks. During this treatment, blood is drawn from the patient to collect white blood cells (T-cells). These cells are genetically modified in a laboratory and then put back into the patient's bloodstream via a slow drip into a vein (intravenously). The modified cells can then target and kill the cancer cells.

Doctors will monitor you or your child closely during and after the treatment.



Plain English Summary

Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia

Who can have tisagenlecleucel?

Patients aged between 2 and 25 years old can have tisagenlecleucel if they have B-cell ALL which has not improved with previous treatment, or has come back after transplant or after at least two previous treatments.

Your doctor or your child's doctor can advise if tisagenlecleucel is a suitable treatment.

Why was tisagenlecleucel recommended for funding?

ACE evaluates how well a treatment works in relation to how much it costs compared to other treatments. Tisagenlecleucel was recommended for funding for certain patients with relapsed or refractory B-cell ALL as it was considered to be an acceptable use of healthcare resources at the price proposed by the company.

What does inclusion on the MOH CTGTP List mean for me?

The MOH CTGTP List includes cell, tissue and gene therapy products that are clinically effective and an acceptable use of healthcare resources. If your doctor or your child's doctor prescribes tisagenlecleucel in line with the funding criteria, the treatment cost will be subsidised. The subsidy levels are available at go.gov.sg/moh-subsidies-for-ctgtps.

Published: 1 August 2024

f Agency for Care Effectiveness - ACE **in** Agency for Care Effectiveness (ACE)

The Agency for Care Effectiveness (ACE) was established by the Ministry of Health (Singapore) to drive better decision-making in healthcare through health technology assessment (HTA), clinical guidance and education. It publishes guidances on diagnosing, treating, and preventing different medical conditions based on the latest research information available worldwide.

This summary is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition.

© Agency for Care Effectiveness, Ministry of Health, Republic of Singapore All rights reserved. Reproduction of this publication in whole or part in any material form is prohibited without the prior written permission of the copyright holder.

To find out more about ACE visit <u>www.ace-hta.gov.sg</u>