

NSW Health Immune Effector Cell Service

Delivering commercial chimeric antigen receptor (CAR)

T-Cell treatment for Diffuse Large B-Cell Lymphoma

Background

NSW Health selected treating centres for the delivery of commercial CAR T-cell therapies in 2020 following approval of this treatment by the Medical Services Advisory Committee (MSAC) of the Australian Government.

Patients aged 25 years or less with refractory or relapsed Acute Lymphoblastic Leukaemia are currently treated with Tisagenlecleucel (Kymriah®) by the Sydney Children's Hospital Network, Royal Prince Alfred and Westmead Hospitals.

Adult patients with refractory or relapsed Diffuse Large B-Cell Lymphoma are now approved for treatment.

Indications for CAR T-Cell Treatment for DLBCL

Patients are eligible if they have relapsed or refractory CD19-positive:

- Diffuse Large B-cell lymphoma (DLBCL)
- Primary Mediastinal Large B-cell Lymphoma (PMBCL)
- Transformed Follicular Lymphoma (TFL).

To be eligible, DLBCL and PMBCL patients must have:

- relapsed after autologous stem cell transplantation OR
- relapsed after, or be refractory to, at least two prior systemic therapies.

Patients with TFL must have relapsed after, or be refractory to, at least two prior systemic therapies administered after disease transformation.

Note: patients who have failed multiple lines of therapy beyond these minimum criteria would be considered eligible.

Patients with DLBCL are also eligible for commercial CAR T-Cell treatment if they have previously transformed from Chronic Lymphocytic Leukemia (CLL) and otherwise satisfy the criteria of relapse after at least two lines of prior therapy following the diagnosis of DLBCL.

The following treatment criteria exist (note, all are required):

- The patient must be treated in a tertiary public hospital with appropriate credentials.
- The patient must be treated by a haematologist working in a multi-disciplinary team specialising in the provision of CAR T-Cell therapy.
- The patient must not have uncontrolled infection, including uncontrolled HIV or active hepatitis B or C infection.
- The patient must not have primary Central Nervous System (CNS) lymphoma.
- The patient must not have uncontrolled secondary CNS disease, or secondary CNS disease anticipated to be uncontrolled at the time of lymphocyte infusion.

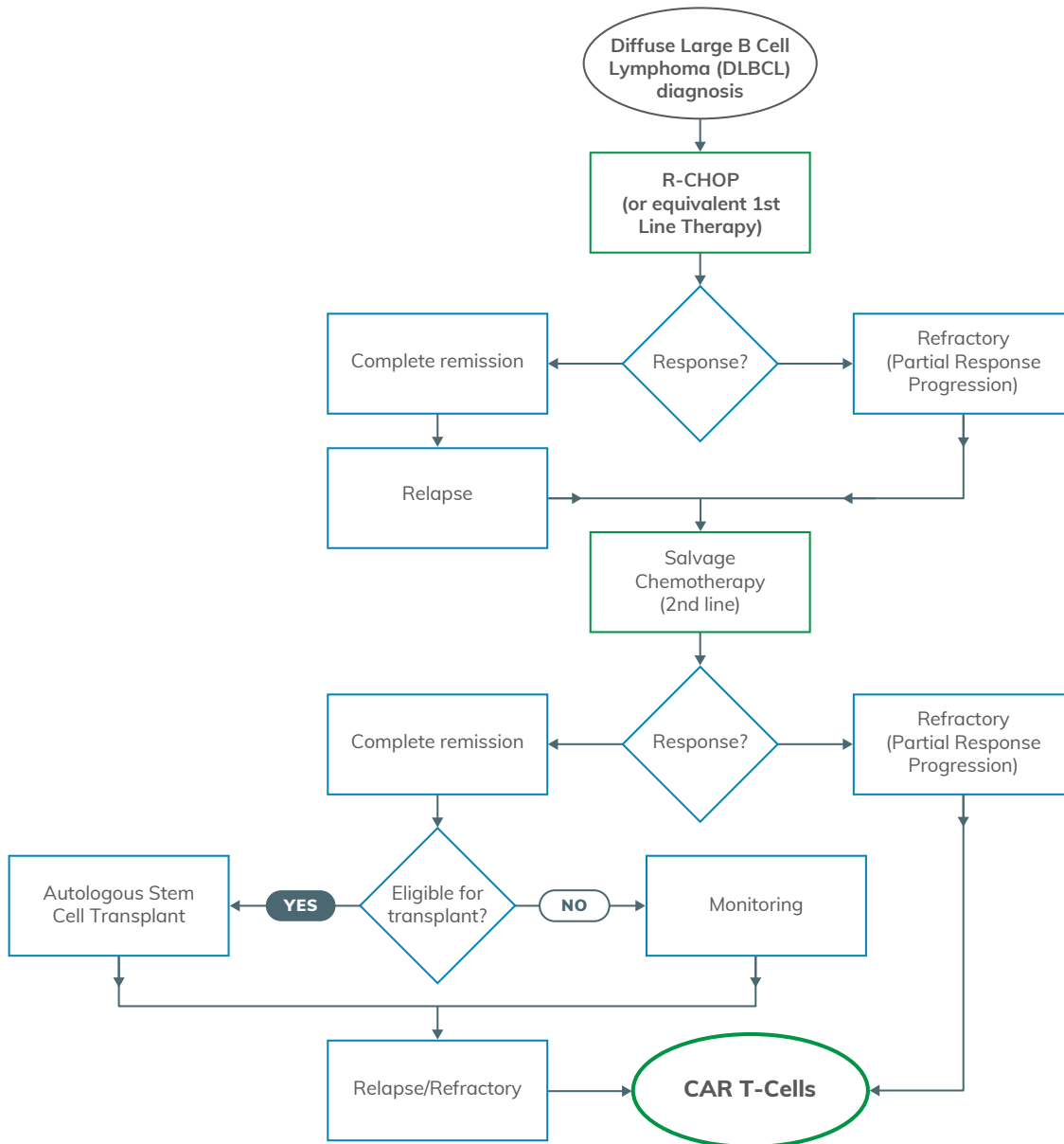
If you have concerns regarding your patient's urgency, relapse status or refractory level, please contact the treating centres listed under Contacts to discuss.

Referrals

A referral should be made by first contacting the treating centres listed under Contacts to discuss your patient. You will be asked to complete a Referral for CAR T-Cell Treatment for DLBCL Checklist. This documents the patient's eligibility and clinical history to assist the treating centre to decide whether the patient meets the clinical criteria.

Treating algorithm

The following algorithm has been developed to reflect the *minimum* approval criteria for the treatment and to assist with referral. Note: therapies in the context of a clinical trial are considered as lines of therapy.



Contacts

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