Independent Hospital Pricing Authority

Chimeric antigen receptor T cell therapy (CAR-T cell): guidelines for costing, counting and reconciliation of funding

June 2020

IHPA

Scope

This document outlines an approach to:

- funding
- counting
- costing
- reconciliation of funding.

Background

Chimeric antigen receptor, or CAR-T cell therapy, is a form of immunotherapy that uses specially altered T cells to directly and precisely target cancer cells.

The Therapeutic Goods Administration (TGA) has approved Novartis' CAR-T product Kymriah (tisagenlecleucel, formerly CTL019). The approved indications are for the treatment of paediatric and young adult patients up to 25 years of age with B-cell precursor acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post-transplant, or in second or later relapse; and for the treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) after two or more lines of systemic therapy.

The CAR-T cell therapy program is currently funded for paediatric and young adults (up to 25 years) with Acute Lymphoblastic Leukaemia (ALL) who relapse or do not respond to initial therapy.

On 31 July 2019 the Commonwealth Minister for Health wrote to the Independent Hospital Pricing Authority Chair to confirm that funding arrangements had been agreed with NSW and Victoria in relation to CAR-T cell therapy.

Broadly the agreed arrangements are:

- Kymriah will be funded through the National Health Funding Pool, with the Commonwealth funding 45% of the cost of the service using block funding.
- The Commonwealth funding will be excluded from the 6.5 per cent cap calculation for 2019-20 and 2020-21.
- The block-funded amounts in the national efficient cost determination will be updated throughout the year, as better data is available following the commencement of provision of treatment.

Patient registration

Patient referral and registration will rely on case based expert clinical opinion and advice, and multi-specialist review. There are a select number of sites nationally that have been established to provide the treatment. In January 2019 Peter MacCallum Cancer Centre, in conjunction with the Royal Children's Hospital, Victoria was accredited to provide the treatment. NSW and Queensland are in the process of accreditation with Novartis of two sites in each state: Royal Prince Alfred Hospital and Sydney Children's Hospital Randwick; and Royal Brisbane and Women's Hospital, and the Children's Hospital respectively. These host sites will be the primary providers of the CAR-T Kymriah treatment. Patients may receive associated care through public hospitals nationally.

Costs associated with CAR-T can be assigned to a patient while they are registered in the program.

Patient age limit

While the decision made by Medical Services Advisory Committee (MSAC) in 2019 specified the treatment was approved for patients up to the age of 25 at the September 2019 workshop the Commonwealth advised that qualified specialists have the discretion to determine at what stage in therapy the age threshold applies.

Block funded amounts

2019-20

IHPA wrote to NSW and Victoria requesting that they provide advice in relation to the costs that they may occur in 2019-20 financial year to be incorporated in the Supplementary National Efficient Cost Determination 2019-20.

The Supplementary National Efficient Cost 2019-20, published December 2019, included the amounts for block funding.

2020-21

In December 2019 IHPA wrote to all jurisdictions requesting that they provide block funded amounts for inclusion in the National Efficient Cost Determination 2020-21 (NEC20). Correspondence with NSW and Victoria specified that this include costs associated with provision of CAR-T therapy for the 2020-21 financial year. Further updates to these figures will be included in the Supplementary National Efficient Cost Determination 2020-21.

In scope activity

In scope activity is provided by hospitals accredited to provide the treatment and includes:

- the establishment and ongoing accreditation of treatment centres
- admitted, non-admitted and emergency department services related to the indication whilst patients are registered on the CAR-T program
- accommodation and transport of the patient, and if required carer, where those costs are incurred by the providing hospital.

In scope activity covers all hospital activity related to the treatment of patients in the pALL cohort undergoing Kymriah therapy and its side effects. This is included in the providing hospital's general ledger.

While it is acknowledged that each patient will have different interactions with the treatment a generic patient pathway was proposed and discussed at the September 2019 workshop. The clinical pathway prepared by Peter MacCallum Cancer Centre (Attachment A) is based on clinical trials and patients currently registered. The pathway identifies three distinct phases of treatment, registration, treatment and follow up. Table 1 summarises the anticipated treatment steps for the CAR-T ALL indication. These steps are not necessarily sequential or exhaustive, and some steps may be repeated

Table 1 Treatment steps for CAR-T

Step	Description	Anticipated activity stream
1	Referral	Non-admitted – patient not present
2	Patient Consultation	Non-admitted
3	CAR-T patient weekly prioritisation meeting	Non-admitted – patient not present
4a	Patient in remission	
4b	Patient relapse	
5a	Pre-emptive Cell Collection* (patient in remission)	Admitted
5b	Cell collection (patient relapse)	Admitted
6	Organ fitness test	Non-admitted
7	Apheresis suitability	Admitted
8	Radiology central line	Admitted
9	Leukapheresis	Admitted
10a	PECC processing	Non-patient
10b	CC processing	
11	Bridging therapy	Admitted
12	Lymphodepleting chemotherapy	Admitted
13	Reinfusion	Admitted
14	Day 1-7 monitoring	Admitted
15	OP monitoring 5 weeks	Non-admitted
16a	Transition to referring centre	Non-admitted
16b	Disease restaging	Admitted
17	Reporting ABMTRR	Non-admitted patient not present

* PECC cells are stored and available if patient relapses.

Out of scope activity

Hospital services provided to patients registered in a CAR-T program by hospitals not registered on the program are out of scope of the block-funded amount. This activity will be funded through activity based funding or block funding of small rural hospitals.

Manufacture failure

Patients who are registered on the program and undergo leukapheresis but are not reinfused will be discharged from the program.

Patients who are registered on the program and are reinfused with sub-optimal Kymriah product will remain registered in the program however, there will be no payment for the Novartis product. Repeat treatment is an option that relies on case based expert clinical opinion and advice, and multi-specialist review.

Pre-emptive cell collection

Patients who undergo pre-emptive cell collection are required to be registered in the program to be considered in-scope for funding.

Costing

Fixed

Fixed costs associated with the provision of CAR-T include minimum staffing requirements and other resources required for a service to be established and maintain accreditation for the MSAC recommended therapy, regardless of the number of patients treated.

Variable

Variable costs are those which can be attributed to a registered patient, directly or indirectly, during the course of their treatment.

Costs are to be submitted and linked to the end class assigned based on the activity based funding (ABF) activity data.

Costing practitioners are recommended to follow the Australian Hospital Patient Costing Standards to ensure that costs are accurately allocated to patients. The current advice provided by jurisdictions is that the Relative Value Units for pathology, and used for allocating costs associated with bed days do not adequately account for the intensive nature of CAR-T treatment.

Accurate costs are required for both forecasting to be included in the national efficient cost determinations as well as to support the reconciliation process.

Submission of activity and cost data

Activity data submission

Activity data is to be submitted quarterly based on the annual ABF data set specifications. Activity data files for CAR-T patients will be included in the ABF data files. Activity information will be reported using National Minimum Data Sets (NMDS) and National Best Endeavours Data Sets (NBEDS), including:

- Admitted patient care NMDS
- Admitted subacute and non-acute hospital care NBEDS
- Non-admitted patient emergency department care NMDS
- Non-admitted patient NBEDS.

Jurisdictions are required to provide an additional data file which includes identifiers so that treatment associated with patients registered in CAR-T programs can be identified in the ABF data sets.

For activity associated with the fixed costs of service provision jurisdictions are required to provide information around this non–patient activity. Activity of CAR-T service provision is to be submitted to IHPA in line with activity data submissions, and should be provided via the EDW drop box. Details to be provided are described in Table 2.

Table 2 Activity of CAR-T service provision

Resource	Descriptor	Count
Establishment identifier		
Staff type		
Medical		
Nursing		
Administration		
Medical and Surgical supplies		
Good and services		
Pharmacy		
Hotel		
Other		

Cost data submission

The cost of services associated with CAR-T cell therapy need to be submitted to IHPA along with Q4 activity data each year. A single NHCDC submission will be provided by jurisdictions. IHPA will link the cost file to the CAR-T ABF files using linking rules used for NHCDC/ABF linking.

IHPA will work with jurisdictions to attribute the fixed costs of services to patients that have been registered on the programme during the financial year. This will be weighted based on stage of treatment and length of time registered in the programme.

The allocation process will be further developed and agreed with jurisdictions.

Funding and reconciliation

Commonwealth funding for CAR-T therapy will be delivered using the National Health Funding Body's payment system. Prospective payments will be made following advice requested from jurisdictions to be included in the national efficient cost determination and supplementary NEC each year as determined by IHPA.

Once the actual volume of patients treated and the associated costs are known IHPA will publish an updated NEC determination, which reconciles between the anticipated and actual costs of the program. Where jurisdictions have spent more than the anticipated amount the determination will include additional funding, where jurisdictions have not spent the anticipated amount the determined costs of treatment will be reduced. The updated NEC determination will be published as soon as practicable after 30 June each year.

Where treatment is provided across reporting periods patient activity is submitted for the reporting period in which the treatment was delivered and funding is allocated or adjusted on that basis.

Other

Statement of Assurance/Data quality statement

Jurisdictions will provide detail in relation to number of patients who are registered on the programme throughout the financial year in their Statement of Assurance. The Data Quality

Statement provided with the NHCDC should confirm that costs associated with CAR-T patients have been allocated correctly and have been attributed to services submitted.

Movement to ABF

The process of moving CAR-T from retrospective reconciled funding to funding within the ABF framework will be explored and recommended through IHPA's Jurisdictional Advisory Committee as patient volumes increase and data becomes available.