MSAC application 1819

Breyanzi (lisocabtagene maraleucel) for the treatment of large B-cell lymphoma

Application for MBS eligible service or health technology

HPP Application number:

HPP200368

Application title:

Breyanzi (lisocabtagene maraleucel) for the treatment of large B-cell lymphoma

Submitting organisation:

BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD

Submitting organisation ABN:

33004333322

Application description

Succinct description of the medical condition/s:

Large B-cell lymphoma (LBCL) is a type of blood cancer impacting specific types of white blood cells known as B-cells. LBCL can affect people of any age, but it occurs mostly in older people.
The condition typically starts as a quickly growing mass in a lymph node but can also start in other areas, such as the intestines, bones, or even the brain or spinal cord. LBCL tends to be a fast-growing (aggressive) lymphoma, but it often responds well to treatment.

Succinct description of the service or health technology:

Lisocabtagene maraleucel (Breyanzi) is chimeric antigen receptor T-cell (CAR-T) therapy. CAR-T therapy is an immunocellular therapy that is individualised to each patient. It involves the leukapheresis of autologous T-cells from a blood sample taken from a patient. The T-cells are then genetically modified via transduction of a viral vector into T-cell DNA (creating a CAR-T). Following transduction, CAR-T cells are expanded to a therapeutic dose, formulated, and cryopreserved. The manufactured CAR-T cells are primed to target antigens on tumours and destroy cancer cells after reinfusion into the patient.

Application contact details

Are you applying on behalf of an organisation, or as an individual?

Organisation

Is the applicant organisation the organisation you are representing in the HPP today?

Yes

Applicant organisation name:

BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD

Application details

Please select the program through which the health technology would be funded:

National Health Reform Agreement Addendum (Highly specialised therapies)

Please provide justification for selecting the above program:

HSTs are Therapeutic Goods Administration (TGA) approved medicines and biologicals delivered in public hospitals where:
• the therapy and its conditions of use are recommended by the Medical Services Advisory Committee (MSAC) or the Pharmaceutical Benefits Advisory Committee (PBAC)
• the average annual treatment cost at the commencement of funding exceeds $200,000 per patient (including ancillary services) as determined by the MSAC or PBAC with input from the Independent Health and Aged Care Pricing Authority (IHACPA)
• the therapy is not otherwise funded through a Commonwealth program, or the costs of the therapy are not appropriately funded through a component of an existing pricing classification (IHACPA, 2025)
To aid the Joint Chairs in their assessment of the appropriate reimbursement pathway for lisocabtagene maraleucel the Sponsor has undertaken a preliminary assessment against each of these criteria.

TGA approved medicines and biologicals
A regulatory submission for lisocabtagene maraleucel was lodged to the TGA on

redacted. Regulatory approval is anticipated in **redacted**.
The submission seeks approval under the class 4 biologicals pathway (in line with existing CAR-T therapies).

Delivered in public hospitals
The planned MSAC submission for lisocabtagene maraleucel anticipates that treatment will be primarily provided in the public hospital setting. In line with existing CAR-T treatment, the Sponsor proposes that existing CAR-T treatment centres that currently provide treatment with axicabtagene ciloleucel and tisagenlecleucel are also appropriate treatment centres for lisocabtagene maraleucel.
There is evidence to support the ability for patients to be treated with lisocabtagene maraleucel in an outpatient capacity, and this is currently occurring in other jurisdictions. At the time of initial reimbursement, it is anticipated that only a small minority of treatment will occur in this manner, but the Sponsor believes the existing eligibility criteria and funding parameters support the ability for an HST to be offered in the outpatient setting in any case.
Evidence supporting the feasibility of outpatient treatment with lisocabtagene maraleucel will be included in the ADAR (and details of relevant clinical trials are presented in the PICO documents alongside this submission).

Therapy and its conditions of use are recommended by the Medical Services Advisory Committee (MSAC) or the Pharmaceutical Benefits Advisory Committee (PBAC)
The Sponsor proposes that an Applicant Developed Assessment Report is submitted to MSAC at the July 2026 deadline, for consideration at the November 2026 MSAC meeting. This allows for the alignment of regulatory approval with MSAC consideration. At this time, the Sponsor proposes a non-inferiority/cost-minimisation approach to existing CAR-T therapies.
Prior considerations of CAR-T therapies have been undertaken by MSAC, noting that CAR-T is not considered to be a pharmaceutical (therefore not applicable for PBAC to consider PBS listing).

Average annual treatment cost at the commencement of funding exceeds $200,000 per patient (including ancillary services) as determined by the MSAC or PBAC with input from the Independent Health and Aged Care Pricing Authority (IHACPA)
At this time, the average annual treatment cost at the commencement of funding is not defined for lisocabtagene maraleucel.

The Sponsor understands that axicabtagene ciloleucel and tisagenlecleucel have been funded as HSTs, indicating that these therapies exceed $200,000 per patient in cost. Given the intended MSAC submission seeks the same price as these therapies, it is logical that this criterion will be met for lisocabtagene maraleucel (if recommended by the relevant reimbursement committee on the proposed cost minimisation basis). The Sponsor welcomes collaboration with IHACPA and State and Territory health departments with regards to the relevant inputs to best inform the per patient cost of treatment with CAR-T.

Therapy is not otherwise funded through a Commonwealth program, or the costs of the therapy are not appropriately funded through a component of an existing pricing classification
Lisocabtagene maraleucel is currently not available in Australia as it is not registered by the TGA. To the Sponsor's knowledge, there is no other existing pricing classification that would form an appropriate mechanism for the funding of lisocabtagene maraleucel.

Based on the above assessment, the Sponsor believes that consideration by MSAC under the HST framework is the appropriate pathway for a reimbursement assessment for lisocabtagene maraleucel.

Is the application for a new listing or a change to an existing listing?

New listing

What is the type of service or health technology?

Therapeutic

PICO sets

Application PICO sets:

PICO set number	PICO set name
1	2L LBCL
2	3L+ LBCL

Application PICO set: 2L LBCL

Population

Describe the population in which the proposed health technology is intended to be used:

Patients with confirmed relapsed/refractory large B-cell lymphoma (LBCL)

Select the most applicable Medical condition terminology (SNOMED CT):

B-cell lymphoma

Intervention

Name of the proposed health technology:

Lisocabtagene maraleucel (Breyanzi®)

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Axicabtagene ciloleucel (Yescarta)

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

Event-free survival (EFS)
Complete response rate (CRR)
Progression-free survival (PFS)
Overall survival (OS)
Duration of response (DOR)
Objective response rate (ORR)
Progression-free survival 2 (PFS-2)
Health related quality of life (HRQoL)

Note that the proposed therapy is not a test.

Specified restrictions for funding

Please add one or more items, with specified restrictions for funding, for each Population / Intervention:

Proposed item:

AAAAA

Is the proposed item restricted?

Yes - restricted

Provide a short description of the restriction:

Restricted via NHRA agreements

Please draft a proposed restriction to define the population and health technology usage characteristics that would define eligibility for funding:

See existing eligibility criteria agreed for axicabtagene ciloleucel (MSAC PSD 1722.1, Table 2). The proposed eligibility criteria for lisocabtagene maraleucel is aligned to this criteria.

Proposed price of supply:

$0.00

Indicate the overall cost per patient of providing the proposed health technology:

$0.00

Provide details and explain:

The proposed price for lisocabtagene maraleucel is the same as axicabtagene ciloleucel, which is not visible to the Sponsor at this time.

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Funded as a Highly Specialised Therapy (HST) under the National Health Reform Agreement (NHRA).

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Non-inferior

Please state what the overall claim is, and provide a rationale:

Claim of non-inferiority is based on the totality of evidence available for lisocabtagene maraleucel in comparison to the nominated comparator, axicabtagene ciloleucel.

Estimated Utilisation

Estimate the prevalence and/or incidence of the proposed population:

Per the MSAC Public Summary Document for axicabtagene ciloleucel, there are an estimated 6,791 R/R LBCL patients in 2024, rising to 7,305 in 2029 (MSAC PSD 1772.1, Table 16).

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

TBC

Year 2 estimated uptake (%):

TBC

Year 3 estimated uptake (%):

TBC

Year 4 estimated uptake (%):

TBC

Estimate the number of patients who will utilise the proposed technology for the first full year:

TBC

Optionally, provide details:

Uptake of lisocabtagene maraleucel has not been estimated at this time, but it is expected that based on the proposed submission approach, a proportion of patients currently treated with axicabtagene ciloleucel in the 2L LBCL setting will be treated with lisocabtagene maraleucel if available.

Will the technology be needed more than once per patient?

No, once only

Application PICO set: 3L+ LBCL

Population

Describe the population in which the proposed health technology is intended to be used:

Patients with confirmed relapsed/refractory large B-cell lymphoma (LBCL)

Select the most applicable Medical condition terminology (SNOMED CT):

B-cell lymphoma

Intervention

Name of the proposed health technology:

Lisocabtagene maraleucel (Breyanzi®)

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Axicabtagene ciloleucel (Yescarta) and tisagenlecleucel (Kymriah)

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

Objective response rate (ORR)
Complete response rate (CRR)
Progression-free survival (PFS)
Overall survival (OS)
Duration of response (DOR)
Health related quality of life (HRQoL)

Note that the proposed therapy is not a test.

Specified restrictions for funding

Please add one or more items, with specified restrictions for funding, for each Population / Intervention:

Proposed item:

AAAAA

Is the proposed item restricted?

Yes - restricted

Provide a short description of the restriction:

Restricted via NHRA agreements

Please draft a proposed restriction to define the population and health technology usage characteristics that would define eligibility for funding:

See existing eligibility criteria agreed for axicabtagene ciloleucel (1676 PSD, Table 2). and tisagenlecleucel. (1587 PSD, Table 1).
The proposed eligibility criteria for lisocabtagene maraleucel is aligned to these criteria.

Proposed price of supply:

$0.00

Indicate the overall cost per patient of providing the proposed health technology:

$0.00

Provide details and explain:

The proposed price for lisocabtagene maraleucel is the same as axicabtagene ciloleucel/tisagenlecleucel, which is not visible to the Sponsor at this time.

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Funded as a Highly Specialised Therapy (HST) under the National Health Reform Agreement (NHRA).

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Non-inferior

Please state what the overall claim is, and provide a rationale:

Claim of non-inferiority is based on the totality of evidence available for lisocabtagene maraleucel in comparison to the nominated comparators, axicabtagene ciloleucel and tisagenlecleucel.

Estimated Utilisation

Estimate the prevalence and/or incidence of the proposed population:

Per the MSAC Public Summary Document for axicabtagene ciloleucel, there are an estimated 6,791 R/R LBCL patients in 2024, rising to 7,305 in 2029 (MSAC PSD 1772.1, Table 16).

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

TBC

Year 2 estimated uptake (%):

TBC

Year 3 estimated uptake (%):

TBC

Year 4 estimated uptake (%):

TBC

Estimate the number of patients who will utilise the proposed technology for the first full year:

TBC

Optionally, provide details:

Uptake of lisocabtagene maraleucel has not been estimated at this time, but it is expected that based on the proposed submission approach, a proportion of patients currently treated with axicabtagene ciloleucel or tisagenlecleucel in the 3L+ LBCL setting will be treated with lisocabtagene maraleucel if available.

The PSD for MSAC consideration 1587 (Table 17) notes that there were an estimated 132 (Year 1) to 188 (Year 6) patients treated with tisagenlecleucel in the 3L+ LBCL setting.

Will the technology be needed more than once per patient?

No, once only

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entities who provide the health technology/service:

AUSTRALASIAN LEUKAEMIA & LYMPHOMA GROUP

AUSTRALIA AND NEW ZEALAND TRANSPLANT AND CELLULAR THERAPIES LIMITED

HAEMATOLOGY SOCIETY OF AUSTRALIA AND NEW ZEALAND

Entity who may be impacted by the health technology/service:

GILEAD SCIENCES PTY LIMITED

NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED

Entities who produce similar products:

HAEMATOLOGY SOCIETY OF AUSTRALIA AND NEW ZEALAND

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

LYMPHOMA AUSTRALIA LIMITED

RARE CANCERS AUSTRALIA LTD

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)? *(if 'Yes' above)*

No

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

No

Is the therapeutic good to be used in the service exempt from the regulatory requirements of the Therapeutic Goods Act 1989?

No

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

No

Is the therapeutic good in the process of being considered by the TGA? *(if 'Yes' above)*

Yes

Please provide the TGA Application ID: *(if in the process of being considered by the TGA)*

Redacted

Please provide the TGA submission date (DD/MM/YYYY):

Redacted