

MSAC application 1835

**Lifileucel for the treatment of
patients with previously treated
unresectable or metastatic melanoma**

Application or referral for other medical service or health technology

HPP Application number:

HPP200446

Application title:

Lifileucel (AMTAGVI) for previously treated unresectable or metastatic melanoma

Submitting organisation:

IOVANCE AUSTRALIA PTY LTD

Submitting organisation ABN:

60683226520

Application description

Succinct description of the medical condition/s:

Treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

Patients have limited treatment options available and represent a significant unmet medical need in advanced melanoma management, as they have exhausted standard firstline and often second and later-line therapeutic approaches.

Succinct description of the service or health technology:

AMTAGVI (Lifileucel) is an autologous T cell immunotherapy containing tumour-infiltrating lymphocytes (TIL) indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

AMTAGVI was first TGA approved for this indication on June 4th 2026

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:

IOVANCE 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:

Advanced melanoma is a serious form of skin cancer that has either spread to other parts of the body (metastatic melanoma) or cannot be removed with surgery (unresectable melanoma). Once melanoma reaches this stage, it can grow quickly and become life-threatening.

Many patients are initially treated with immunotherapy drugs (such as pembrolizumab, nivolumab, ipilimumab or relatlimab) or targeted therapies (for patients with a BRAF mutation). However, some patients' cancer continues to grow despite these treatments. When standard treatments stop working, there are very limited effective options available, and outcomes are generally poor. This group of patients represents a high unmet medical need.

Lifileucel (AMTAGVI) is a one-time personalised cell therapy made from a patient's own immune cells taken directly from their tumour tissue, that is obtained during surgery.

Before receiving lifileucel, patients receive chemotherapy to facilitate the graftment of lifileucel. Once the chemotherapy course is completed, the lifileucel is infused. Post-infusion, patients are then given a short course of a medicine called interleukin-2 to help the lymphocyte cells grow and expand in their body. The goal of this treatment is to increase the number of active and melanoma-specific T cells to attack and kill the cancer cells. Unlike standard treatments that are given repeatedly over

many months, lifileucel is delivered as a single treatment course in a specialised hospital setting.

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 name
Lifileucel (AMTAGVI) for previously treated unresectable or metastatic melanoma

Population

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

The proposed health technology is intended for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. These patients have limited treatment options available and represent a significant unmet medical need in the management of advanced melanoma.

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

Metastatic malignant melanoma

Intervention

Name of the proposed health technology:

Lifileucel (AMTAGVI)

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:

Ipilimumab plus nivolumab; potentially best supportive care (BSC)

Outcomes

Outcome description:

The proposed outcomes focus on demonstrating meaningful clinical benefit in a heavily pre-treated population with limited remaining treatment options. Outcomes are listed below in order of importance.

1. Overall Response Rate (ORR) and Duration of Response (DoR)
2. Overall Survival (OS)
3. Progression-Free Survival (PFS) – The time before the cancer worsens. This reflects disease control and delays the need for further therapy
4. Safety outcomes – Incidence, severity, and timing of emergence of adverse events (particularly Grade 3+ events) and treatment-related mortality related to the treatment regimen

Lifileucel represents a fundamental change in management from ongoing systemic therapy (such as repeated immunotherapy infusions) to a one-time personalised cellular therapy. Responding patients may no longer require continuous drug administration or ongoing side-effect management, resulting from systemic therapies administered over prolonged periods of time. Evidence of meaningful clinical benefit—particularly durable response and long term survival—supports justification of adoption.

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:

Unresectable or metastatic melanoma

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

For the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

Proposed price of supply:

REDACTED

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

REDACTED

Provide details and explain:

For contextual purposes, the publicly reported United States list price for AMTAGVI is approximately USD \$612,580. When converted to Australian dollars, this provides a broad reference point only. It is important to note that lovance does not expect the Australian price to reflect the US price, and any final pricing in Australia would be subject to reimbursement negotiations with relevant Australian funding bodies, including Commonwealth and State jurisdictions.

The overall cost per patient of providing the proposed health technology will be formally estimated through the economic modelling to be developed as part of the MSAC submission, which will incorporate all relevant cost components, including manufacturing, hospitalisation, supportive care, and associated resource use.

At this stage, anticipated out-of-pocket costs for patients have not yet been determined. It is expected that, if publicly funded, efforts would be made to minimise patient out-of-pocket expenses, consistent with current arrangements for other high-cost cancer therapies delivered within the Australian healthcare system.

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

Lifileucel is not currently listed on the Pharmaceutical Benefits Scheme (PBS) in Australia and is not routinely funded through Medicare or State-based hospital funding arrangements.

There is currently no established public reimbursement mechanism in Australia for this therapy outside of research or sponsor-supported access programs.

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)?

Superior

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

Lifileucel is claimed to be clinically superior to the nominated comparators (nivolumab–ipilimumab retreatment and Best Supportive Care) in terms of overall health outcomes, based on the following considerations:

1. Clinically meaningful efficacy in a refractory population with poor prognosis

The pivotal C-144-01 study demonstrated that lifileucel produces objective and durable tumour responses in a heavily pre-treated population who had progressed following standard therapies, including anti-PD-1 and (where relevant) BRAF±MEK inhibitors. This population typically has limited effective treatment options and poor expected outcomes, and historical response rates with available therapies are low. The observed response rates and long-term survival signals therefore represent a clinically meaningful improvement over expected outcomes with current care

2. Evidence of durability and long-term survival benefit

Lifileucel demonstrates durable responses and a long-term survival plateau, with approximately 20% of patients alive at 5 years in follow-up analyses. This suggests the potential for long-term disease control or remission, which is not commonly achieved with existing later-line therapies. Durable responses are particularly important in advanced melanoma and support a claim of superior long term benefit.

Estimated utilisation

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

lovance estimates an incidence of around REDACTED patients in Australia with unresectable or metastatic melanoma fit the indication and at steady state, REDACTED of patients meeting the indication will receive AMTAGVI.

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

Year 1 estimated uptake (%):

REDACTED

Year 2 estimated uptake (%):

REDACTED

Year 3 estimated uptake (%):

REDACTED

Year 4 estimated uptake (%):

REDACTED

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

REDACTED

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:

MELANOMA INSTITUTE AUSTRALIA

MEDICAL ONCOLOGY GROUP OF AUSTRALIA

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

MELANOMA INSTITUTE AUSTRALIA

MEDICAL ONCOLOGY GROUP OF AUSTRALIA

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

Australian Melanoma & Skin Cancer Alliance (AMSCA)

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)?

Yes

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

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
527457	T cells - Lifileucel, cryopreserved - T - Amtagvi

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

Yes