

Effective July 1, 2024

<p><b>Prior Authorization Required</b> If <u>REQUIRED</u>, submit supporting clinical documentation pertinent to service request.</p>	<p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>
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**Applies to:**

**Commercial Products**

Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

Tufts Health Plan Commercial products; Fax 617-673-0988  
CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

**Senior Products**

Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956

Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

**Overview**

Melanoma is one of the most aggressive skin cancers and may spread in an unpredictable manner to involve virtually any organ of the body. Prognosis is informed by pathologic features such as ulceration, thickness, and if it has spread. Most melanomas arise as superficial, indolent tumors that are confined to the epidermis, however those that infiltrate deep into the dermis have the potential to metastasize. Melanoma accounts for only about 1% of skin cancers but causes a large majority of skin cancer deaths. It is the fifth most common cancer in males and females, and its incidence increases with age. About 100,640 new melanomas will be diagnosed in the US in 2024. The median survival of patients with metastatic melanoma is six to nine months after diagnosis.

Melanoma treatment depends on the stage of disease. Patients with locally or regionally confined melanoma may be treated with surgical excision and management of lymph nodes as necessary. For patients with unresectable or metastatic melanoma systemic treatment is required and may include radiation, chemotherapy, and immunotherapy however prognosis is often poor.

**Food and Drug Administration (FDA) Approved Indications:**

- AMTAGVI is a tumor-derived autologous T cell immunotherapy 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 is to be administered in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

**Clinical Guideline Coverage Criteria**

The Plan may cover Amtagvi for members when the Provider provides documentation of **all** the following:

1. Appropriate diagnosis; **and**
2. Trials of all appropriate alternatives whose manufacturers participate in the federal rebate program; **and**

- Clinical rationale for the use of a drug whose manufacturer does not participate in the federal rebate program

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## Codes

The following code(s) require prior authorization:

**Table 1: HCPCS Codes**

HCPCS Codes	Description
	None

## References:

- Chesney J, Lewis KD, Kluger H, et al. Efficacy and safety of lifileucel, a one-time autologous tumor-infiltrating lymphocyte (TIL) cell therapy, in patients with advanced melanoma after progression on immune checkpoint inhibitors and targeted therapies: pooled analysis of consecutive cohorts of the C-144-01 study. *J Immunother Cancer*. 2022;10(12):e005755. doi:10.1136/jitc-2022-005755.
- Amtagvi (lifileucel). [package insert]. Philadelphia, PA: lovance Biotherapeutics; Feb 2024.

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## Approval And Revision History

May 15, 2024: Reviewed by the Medical Policy Approval Committee (MPAC), effective July 1, 2024

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## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.