

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Amtagvi (lifileucel)</u>
<u>Drugs</u>	<u>Amtagvi (lifileucel)</u>
<u>Covered Uses</u>	<u>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</u>
<u>Exclusion Criteria</u>	<ul style="list-style-type: none"> • <u>Uncontrolled brain metastases</u> • <u>Melanoma of uveal or ocular origin</u> • <u>Systemic steroid therapy for any reason</u>
<u>Required Medical Information</u>	<u>See “Other Criteria”</u>
<u>Age Restrictions</u>	<u>According to package insert</u>
<u>Prescriber Restrictions</u>	<u>Prescriber must be an oncologist</u>
<u>Coverage Duration</u>	<u>If all of the criteria are met, the initial request will be approved for a one-time treatment.</u>
<u>Other Criteria</u>	<p><u>**Drug is being requested through the member’s medical benefit**</u></p> <p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • <u>Diagnosis of unresectable or metastatic melanoma (Stage IIIc or Stage IV)</u> • <u>Member must have progressed through at least one prior systemic therapy including a PD-1/PD-L1 blocking antibody and, if BRAF V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor</u> • <u>Member must have at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection</u> • <u>Eastern Cooperative Oncology Group (ECOG) score of 0 or 1</u> • <u>Medication is prescribed at an FDA approved dose</u> <p><u>The safety and effectiveness of repeat administration of Amtagvi has not been evaluated and will not be approved.</u></p>
<u>Revision/Review Date: 4/2024</u>	<u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u>