CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Afamitresgene Autoleucel (Tecelra®)

Version: 1.0

EFFECTIVE DATE: 11/1/2024

NantHealth® | Eviti®

Please note the following:

Afamitresgene Autoleucel (Tecelra®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Afamitresgene Autoleucel (Tecelra): Discussion

Afamitresgene autoleucel is a human leukocyte antigen-restricted autologous T cell therapy targeting melanoma-associated antigen A4 (MAGE-A4).[1] Afamitresgene autoleucel is a melanoma-associated antigen A4 (MAGE-A4)-directed 13 genetically modified autologous T cell immunotherapy.[2]

Melanoma-associated antigen A4 (MAGE-A4) is a member of the MAGE protein family of cancer/testis antigens, with expression in healthy tissue restricted to immune-privileged sites. MAGE-A4 is expressed in solid cancers, including synovial sarcoma (SS), myxoid/round cell liposarcoma (MRCLS), non-small-cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), ovarian, urothelial, melanoma, and gastroesophageal cancers. MAGE-A4 is intracellularly processed, resulting in peptide fragments that are co-presented with human leukocyte antigens (HLAs) on the cell surface, forming epitopes that are weakly recognized by low-affinity natural T cell receptors (TCRs).[1]

The most common adverse reactions associated with afamitresgene autoleucel in ≥ 20% of the patients included cytokine release syndrome, nausea, vomiting, fatigue, infections, pyrexia, constipation, dyspnea, abdominal pain, non-cardiac chest pain, decreased appetite, tachycardia, back pain, hypotension, diarrhea, edema, and grade 3 or 4 laboratory abnormalities.

Afamitresgene autoleucel is contraindicated in adults who are heterozygous or homozygous for HLA-A*02:05P.

Afamitresgene autoleucel is approved by the Food and Drug Administration (FDA) for synovial sarcoma.[2]

The National Comprehensive Cancer Network (NCCN) endorses afamitresgene autoleucel for soft tissue sarcoma.[3]

Afamitresgene Autoleucel: Definitions

- **National Comprehensive Cancer Network (NCCN)** - An alliance of more than 30 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Food and Drug Administration (FDA)** - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **HLA-A*02:05P** - An allele of the HLA-A gene, which is part of the human leukocyte antigen (HLA) system. These are involved in presenting antigenic peptides to CD8(+) cytotoxic T lymphocytes (CTLs), which is crucial for cellular immunity during viral infections and cancers.[4]

Afamitresgene Autoleucel: Policy

Note: Coverage of afamitresgene autoleucel will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Afamitresgene Autoleucel will be considered for coverage when the following criteria are met:

Synovial Sarcoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Unresectable or metastatic synovial sarcoma 15 who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, 16 -A*02:03P, or -A*02:06P positive and whose tumor expresses the 17 MAGE-A4 antigen[2]; OR

Soft Tissue Sarcoma - Extremity/Body Wall, Head/Neck, Retroperitoneal/Intra-Abdominal

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **NCCN** required criteria coverage:

3. Single agent for palliative treatment for subsequent lines of therapy for advanced/metastatic disease with disseminated metastases (synovial sarcomas only)

and HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive and whose tumor expresses the MAGE-A4 antigen.[3]

Authorization Period and Renewal Criteria

Afamitresgene autoleucel is a one-time dose and will not be renewed.

Afamitresgene Autoleucel: References

1. Hong et al Autologous T cell therapy for MAGE-A4$^+$ solid cancers in HLA-A*02$^+$ patients: a phase 1 trial. https://pubmed.ncbi.nlm.nih.gov/36624315/. Accessed September 24, 2024.
2. Afamitresgene autoleucel Package Insert. https://www.fda.gov/media/180565/download?attachment. Accessed September 24, 2024.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed November 27, 2024.
4. Chen et al Structural and functional distinctiveness of HLA-A2 allelic variants. https://pubmed.ncbi.nlm.nih.gov/22434516/. Accessed November 27, 2024.

Afamitresgene autoleucel: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

Code	Description
C49.0, C49.21	Metastatic synovial sarcoma
C49.3	Synovial sarcoma
C49.9	Soft Tissue Sarcoma
C9399, J9999	Afamitresgene autoleucel

Afamitresgene Autoleucel: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	12/1/2024
2	Policy Review Dates:	
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee:	12/21/2024
6	Revision Changes:	