Reference number(s)
6580-A

SPECIALTY GUIDELINE MANAGEMENT

TECELRA (afamitresgene autoleucel)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Tecelra is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are human leukocyte antigen (HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P) positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Documentation of chart notes, medical record documentation or claims history supporting previous lines of therapy
B. Documentation of laboratory report confirming HLA allele and MAGE-A4 antigen status.

III. CRITERIA FOR INITIAL APPROVAL

Synovial Sarcoma
Authorization of 3 months may be granted for treatment of unresectable or metastatic synovial sarcoma in members 18 years and older when all of the following criteria are met:
1. The member has received prior treatment with chemotherapy
2. The tumor is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P allele positive
3. The tumor expresses the MAGE-A4 antigen
4. The member has not received previous treatment with the requested medication
5. The member is not heterozygous or homozygous for HLA-A*02:05P
6. The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
7. The member has adequate and stable cardiac and kidney function
8. The member has not had an allogeneic hematopoietic stem cell transplant
9. The member does not have a clinically significant active infection and/or inflammatory disorder

IV. REFERENCES
1. Tecelra [package insert]. Philadelphia, PA: Adaptimmune, LLC; August 2024.