Reference number(s)
6580-A

Specialty Guideline Management
Tecelra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tecelra	afamitresgene autoleucel

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[1]

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.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of chart notes or medical record documentation demonstrating failure of previous lines of therapy
- Documentation of laboratory report confirming HLA allele and MAGE-A4 antigen status.

Coverage Criteria

Synovial Sarcoma[1]

Authorization of 3 months (one time dose) 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:

- The member has received prior treatment with chemotherapy
- The tumor is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P allele positive
- The tumor expresses the MAGE-A4 antigen
- The member has not received previous treatment with the requested medication
- The member is not heterozygous or homozygous for HLA-A 02:05P
- The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- The member has adequate and stable cardiac and kidney function
- The member has not had an allogeneic hematopoietic stem cell transplant
- The member does not have a clinically significant active infection and/or inflammatory disorder

References

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