

# 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<sup>1</sup>

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:

Reference number(s)
6580-A

- Documentation of chart notes, medical record documentation or claims history supporting previous lines of therapy
- Documentation of laboratory report confirming HLA allele and MAGE-A4 antigen status.

## Coverage Criteria

### Synovial Sarcoma<sup>1</sup>

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:

- 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.