Reference number(s)
6581-A

Standard Medicare Part B 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- A02:01P, -A02:02P, -A02:03P, or -A02:06P) positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

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- 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-A02:01P, HLA-A02:02P, HLA-A02:03P, or HLA-A02:06P 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-A02:05P
- 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

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Tecelra.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Soft Tissue Sarcoma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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References

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

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