Draft New Policy: Do Not Implement

Afamitresgene Autoleucel (TECELRA®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

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

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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

EFFECTIVE DATE

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