CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs

Tecelra (afamitresgene autoleucel)

Effective: April 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Synovial sarcoma is a relatively rare, but aggressive type of soft tissue sarcoma with a high potential for metastasis. Synovial sarcoma originally received its name from a histologic similarity to synovial cells, however its cell of origin is unknown. Although the cause of synovial sarcoma is not yet clearly defined, tumor cells in more than 90% of patients have a translocation involving chromosome 18 and chromosome X. Synovial sarcoma accounts for 5% to 10% of soft tissue sarcoma cases diagnosed annually in the United State. The incidence is estimated to be 900 new cases a year in the United States. Although synovial sarcoma can appear at any age, it appears to occur more commonly in adolescents and adults younger than 40. It is considered the most common sarcoma in the adolescent age group. The majority of synovial sarcomas are slow growing and the average duration of symptoms before diagnosis is approximately 2 years. While most patients initially present with localized disease, approximately half of these patients will progress to metastatic synovial sarcoma, which is usually incurable.

Synovial Sarcoma can occur anywhere in the body, however in many cases, synovial sarcoma begins from deep soft tissues of extremities such as the leg, arm, or foot, and near joints such as the knee and ankle. Synovial sarcoma typically appears with a mass, often deep-seated, growing with or without pain. Due to the diverse locations and symptoms of tumors, their gradual onset, and the fact that they often appear in younger patients, initial clinical misdiagnosis is possible. Treatment is dependent on the location, grade, and stage. Local tumors can typically be treated with surgery. Treatments for metastatic synovial sarcoma include chemotherapy and targeted therapy. T-cell receptor (TCR) gene therapy is an advanced form of immunotherapy designed to treat certain types of cancer. TCR gene therapy uses genetically modified lymphocytes that are directed against specific tumor markers.

Food and Drug Administration (FDA) Approved Indications:

- 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 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.

Following treatment with Tecelra, monitor patients for at least 7 days at the healthcare facility for cytokine release syndrome (CRS). Continue to monitor patients for CRS for at least 4 weeks following treatment with Tecelra. Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care. Ensure that healthcare providers administering Tecelra have immediate access to medications and resuscitative equipment to manage CRS.

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members and CMS for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations. When CMS and MassHealth do not provide guidance, the Plan's internally developed medical necessity guidelines are used. CMS coverage guidelines are not established for this service. Point32Health covers Tecelra in accordance with MassHealth coverage criteria.

For the therapy Tecelra, evidence is sufficient for coverage. Tecelra received FDA approval in August 2024 supported by the results of the SPEARHEAD-1 phase 2, multicenter open- label, single arm trial. Of those who participated in the trial, there was

an overall response rate of 43.2%, with a complete response rate of 4.5% and partial response rate of 38.6%. The median duration of response was 6 months, and among patients who were responsive to treatment, 39% had a duration of response of 12 months or longer. Tecelra provides an additional treatment option for a very specific patient population with synovial sarcoma.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan may cover Tecelra when all the following clinical criteria is met:

1. The Member has a diagnosis of unresectable or metastatic synovial sarcoma.

AND

2. The Member is ≥ 18 years of age on treatment day.

AND

3. The Prescriber is an oncologist.

AND

4. Documentation of HLA-A*02:01P, -A*02:02P, -A*02:03P, or - A*02:06P positive tumor.

AND

5. Tumor expresses the MAGE-A4 antigen.

AND

6. Inadequate response or adverse reaction to ONE or a contraindication to ALL prior chemotherapy

AND

7. Appropriate dosing and treatment dates

AND

8. Infusion will take place in a qualified treatment facility.

Limitations

- Any indications for Tecelra other than those outlined above are considered investigational and will not be covered.
- Authorization of Tecelra is limited to one single dose treatment

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
Q2057	Afamitresgene Autoleucel, Including Leukapheresis And Dose Preparation Procedures, Per Therapeutic Dose

References:

1. Tecelra (afamitresgene autoleucel) [package insert]. Philadelphia, PA. Adaptimmune, LLC. August 2024.
2. D'Angelo SP, Araujo DM, et. al. Afamitresgene autoleucel for advanced synovial sarcoma and myxoid round cell liposarcoma (SPEARHEAD-1): an international, open-label, phase 2 trial. Lancet. 2024 Apr 13;403(10435):1460-1471. doi: 10.1016/S0140-6736(24)00319-2. Epub 2024 Mar 27. PMID: 38554725; PMCID: PMC11419333.
3. Aytekin MN, Öztürk R, et. al. Epidemiology, incidence, and survival of synovial sarcoma subtypes: SEER database analysis. J Orthop Surg (Hong Kong). 2020 Jan-Apr;28(2):2309499020936009. doi: 10.1177/2309499020936009. PMID: 32618221.
4. Gazendam AM, Popovic S, et. al. Synovial Sarcoma: A Clinical Review. Curr Oncol. 2021 May 19;28(3):1909-1920. doi: 10.3390/curroncol28030177. PMID: 34069748; PMCID: PMC8161765.
5. Hayes, Inc. Emerging Technology Report. Afamitresgene Autoleucel (Tecelra; Adaptimmune LLC) for Advanced Synovial Sarcoma. August 6, 2024. Available at hayesinc.com. Last accessed September 20, 2024.
6. Pokras S, Tseng WY, et. al. Treatment patterns and outcomes in metastatic synovial sarcoma: a real-world study in the US oncology network. Future Oncol. 2022 Oct;18(32):3637-3650. doi: 10.2217/fon-2022-0477. Epub 2022 Aug 26.

PMID: 36018238.
7. Mangla A, Gasalberti D. Synovial Cell Sarcoma. 2023 May 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan–. PMID: 36508540.

Approval And Revision History

February 19, 2025: Reviewed by the Medical Policy Approval Committee (MPAC), effective April 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.