Updated Prior Authorization Requirements for Chimeric Antigen Receptor (CAR) T-cell Therapy

Information posted March 29, 2019

**Note:** Texas Medicaid managed care organizations (MCOs) must provide all medically necessary, Medicaid-covered services to eligible clients. Administrative procedures such as prior authorization, pre-certification, referrals, and claims/encounter data filing may differ from traditional Medicaid (fee-for-service) and from MCO to MCO. Providers should contact the client's specific MCO for details.

Beginning April 1, 2019, prior authorization criteria will change for Chimeric Antigen Receptor T-cell Therapy (CAR-T) Axicabtagene ciloleucel (Yescarta) (procedure code Q2041) and Tisagenlecleucel (Kymriah) (procedure code Q2042) infusions.

**Overview**

Axicabtagene ciloleucel (Yescarta) (procedure code Q2041) and Tisagenlecleucel (Kymriah) (procedure code Q2042) must be prescribed by an oncologist or in consultation with an oncologist and treatment must take place at a certified health-care facility.

Certified health-care facilities must ensure that providers who prescribe, dispense, or administer Axicabtagene ciloleucel (Yescarta) and Tisagenlecleucel (Kymriah) receive training on the management of cytokine release syndrome (CRS) and neurological toxicities.

Certified health-care facilities must enroll in and comply with the Risk Evaluation and Mitigation Strategies (REMS) program requirements for each drug administered under this policy.

Severe or life-threatening CRS must be treated with tocilizumab. The health-care facility must have at least two doses of tocilizumab on site per patient, for administration within two hours of infusion, for treatment of CRS.

Providers and health-care facilities must ensure that the patient receives the recommended treatment pre-medications and monitor the patient closely for toxicity post-infusion. The patient must be instructed to remain in proximity of the certified health-care facility for at least four weeks post-infusion.

**Added Prior Authorization Criteria for Axicabtagene Ciloleucel (Yescarta)**

The following prior authorization criteria for Axicabtagene Ciloleucel (Yescarta) (procedure code Q2041) will be added as requirements for infusion therapy:

- The client is 18 years old or older.
• The client does not have primary central nervous system lymphoma disease.
• The client does not have an active infection or inflammatory disorder.
• The client has not received prior CAR-T therapy.

**Added Prior Authorization Criteria for Tisagenlecleucel (Kymriah)**

The following prior authorization criteria for Tisagenlecleucel (Kymriah) (procedure code Q2042) infusion will be added for the treatment of clients with refractory or second relapse B-cell precursor acute lymphoblastic leukemia (ALL):

• The client has a confirmed diagnosis of B-cell ALL (diagnosis codes C9100, C9101, and C9102).
• The client is age 25 years or younger.
• The client has a confirmed CD-19 tumor expression.
• The disease is refractory, or in second or later relapse.
• Eastern Cooperative Oncology Group performance status of 0 to 3.
• The client has not received prior CAR-T therapy.

The following prior authorization criteria Tisagenlecleucel (Kymriah) (procedure code Q2042) infusion will be added for the treatment of clients with relapsed or refractory diffuse large B-cell lymphoma:

• The client has a confirmed diagnosis of relapsed or refractory large B-cell lymphoma (diagnosis codes C8330, C8331, C8332, C8333, C8334, C8335, C8336, C8337, C8338, and C8339):
  o Diffuse large B-cell lymphoma, not otherwise specified
  o High grade B-cell lymphoma
  o Diffuse large B-cell lymphoma arising from follicular lymphoma
• The client is 18 years old or older.
• The client must have relapsed or refractory disease as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant).
• The client must have received adequate prior therapy including, at a minimum, the following criteria:
  o An anthracycline-containing chemotherapy regimen
  o For CD20+ disease, an anti-CD20 monoclonal antibody
  o For clients with transformed follicular lymphoma, prior chemotherapy refractory disease after transformation to DLBCL
• Eastern Cooperative Oncology Group performance status of 0 or 1.
• The client does not have primary central nervous system lymphoma.
• The client does not have an active infection or inflammatory disorder.
• The client has not received prior CAR-T therapy.

Limitation Criteria for Procedure Code Q2042

Effective May 1, 2019, procedure code Q2042 will be limited to once per lifetime, any provider.

Documentation Requirements

All services outlined above are subject to retrospective review to ensure that the documentation in the client’s medical record supports the medical necessity of the service(s) provided.

Exclusions

Axicabtagene ciloleucel (Yescarta) and Tisagenlecleucel (Kymriah) may not be a benefit for clients with the following criteria:
• An active infection or inflammatory disorder
• Primary central nervous system lymphoma

For more information, call the TMHP Contact Center at 1-800-925-9126.