MassHealth Chimeric Antigen Receptor (CAR)-T Immunotherapies Monitoring Program

The following chimeric antigen receptor (CAR)-T immunotherapies require prior authorization (PA) and will be managed by the CAR-T Monitoring Program.

CAR-T Agent	Food and Drug Administration (FDA)-approved Indications and Limitations of Use
Abecma (idecabtagene vicleucel)	• Treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
Breyanzi (lisocabtagene maraleucel)	• Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS) (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. • *Limitation of Use*: Not indicated for the treatment of patients with primary central nervous system lymphoma.
Carvykti (ciltacabtagene autoleucel)	• Treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
Kymriah (tisagenlecleucel)	• Treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. • Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL NOS, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL). • *Limitation of Use*: Not indicated for the treatment of patients with primary central nervous system lymphoma.
Tecartus (brexucabtagene autoleucel)	• Treatment of adult patients with relapsed or refractory B-cell precursor ALL. • Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

CAR-T Agent	Food and Drug Administration (FDA)-approved Indications and Limitations of Use
Yescarta (axicabtagene ciloleucel)	• Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL NOS, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. • Treatment of adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. • *Limitation of Use*: Not indicated for the treatment of patients with primary central nervous system lymphoma. • Treatment of adult patients with relapsed or refractory FL after two or more lines of systemic therapy

CAR-T Therapies

In order to create CAR-T therapies, a patient's own T-cells are frozen and sent to the manufacturing facility for cell processing. These T-cells are manipulated ex vivo to express antigens which activate T-cell response. Then, they are infused back into the patient as a one-time infusion.

Patients must stay within close proximity (within two hours) of the treatment site for at least four weeks after infusion for monitoring. Abecma, Breyanzi, Kymriah, Tecartus, and Yescarta treatment may only be provided at healthcare facilities certified pursuant to the Risk Evaluation and Mitigation Strategy (REMS) program specific to the treatment being provided. The treatments' respective REMS programs were created to ensure that hospitals and associated clinics are specially certified, that such facilities have on-site immediate access to Actemra (tocilizumab), and to ensure that those who prescribe, dispense, or administer CAR-T therapies are aware of how to manage the risks of cytokine release syndrome (CRS) and neurological toxicities.

CAR-T Monitoring Program

CAR-T therapies will require PA. These therapies are administered by a one-time infusion and the durability of response is currently unknown given the recent FDA-approval of these agents. As such, MassHealth Drug Utilization Review (DUR) will be reaching out to prescribers approximately 30 days after the CAR-T infusion date to verify clinical effectiveness and at ongoing intervals for long-term monitoring of sustained response.

Following PA approval, MassHealth DUR will outreach to the prescriber to inform of the CAR-T Monitoring Program and fax information to assist prescribers reporting member outcomes following CAR-T infusion.

Approximately 30 days following CAR-T infusion, the prescriber will need to submit documentation of leukapheresis, hospital admission for CAR-T infusion, CAR-T infusion, and hospital discharge dates, and indicate whether the member experienced adverse reactions such as CRS and neurological toxicities and whether the member required treatment for adverse reactions in the intensive care unit setting. The prescriber will also need to submit evidence documenting the member's response to treatment.

DUR will be outreaching at ongoing intervals in order to conduct long term monitoring for CAR-T therapies. Prescribers will inform DUR at these intervals whether the member continues to have ongoing response or has relapsed.

1. Abecma [package insert]. Summit (NJ): Celgene; 2021 Mar.
2. Breyanzi [package insert]. Bothell (WA): Juno Therapeutics; 2021 Feb.
3. Kymriah [package insert]. East Hanover (NJ): Novartis Pharmaceuticals; 2021 Aug.
4. Tecartus [package insert]. Santa Monica (CA): Kite Pharma, Inc; 2021 Oct.
5. Yescarta [package insert. Santa Monica (CA): Kite Pharma, Inc.; 2022 Apr.
6. Maude SL, Laetsch TW, Buechner J, Rives S, Boyer M, Bittencourt H, et al. Tisagenlecleucel in Children and Young Adults with B-Cell Lymphoblastic Leukemia. N Engl J Med. 2018 Feb 1;378(5):439-448. doi: 10.1056/NEJMoa1709866.
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8. Neelapu SS, Locke FL, Bartlett NL, Lekakis LJ, Miklos DB, Jacobson CA, et al. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. N Engl J Med. 2017 Dec 28;377(26):2531-2544. doi: 10.1056/NEJMoa1707447. Epub 2017 Dec 10.
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12. Munshi NC, Anderson Jr LD, Shah N, Madduri D, Berdeja J, Lonial S et al. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. N Engl J Med. 2021 Feb 25;384(8):705-716
13. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Multiple Myeloma Version 5.2022 [guideline on the internet]. Fort Washington, Pennsylvania: National Comprehensive Cancer Network; 2022 Mar 9 [cited 2022 Apr 7]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf.
14. Carvykti [package insert]. Horsham (PA): Janssen Biotech, Inc.; 2022 Feb.