Subject: Chimeric Antigen Receptor (CAR) T-cell Therapy

Medical Policy #: 32.0

Original Effective Date: 03/27/2019

Status: Reviewed

Last Annual Review Date: 08/21/2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Chimeric antigen receptor (CAR) T-cells and genetically engineered T-cell receptor (TCR) T-cells are manufactured by collecting lymphocytes from a patient donor and modifying them ex vivo through gene transfer techniques. Viral vectors are introduced that express cell receptors that are highly specific for the individual's tumor antigens. CAR T-cells, express a hybrid receptor with an extracellular single-chain antibody fragment, a transmembrane domain, and at least 1 intracellular signaling domain. CAR T and TCR T cells are then infused back into a patient's body, where they direct a targeted immune response to cancerous tissue. CAR T-cells are most often used to treat hematological malignancies, and a common target is B-cell cluster of differentiation antigen19 (CD19).

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

Coverage for Commercial, Centennial and Medicare.

Presbyterian uses Optum Car T-Cell Therapy Clinical Guidelines.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description (See also Optum
Q2041	Axicabtagene Ciloleucel (**Yescarta**), up to 200 Million Autologous Anti-CD19 CAR positive T Cells, including Leukapheresis and dose preparation procedures, per therapeutic dose.
Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose (**Kymriah**).
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose (Pass-Through Drugs and Biologicals) (Pass-Through Drugs) (**TECARTUS**)
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose (**BREYANZI)**
Q2055	Idecabtagene vicleucel, up to 460 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose **(ABECMA)**
Q2056	Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose (**Carvykti**)
0537T	Chimeric antigen receptor T-cell therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day. (collection/handling)
0538T	Chimeric antigen receptor T-cell therapy; preparation of blood-derived T lymphocytes for transportation. (preparation for transport)

CPT Codes	Description (See also Optum
0539T	Chimeric antigen receptor T-cell therapy; receipt and preparation of CAR-T cells for administration.
0540T	Chimeric antigen receptor T-cell therapy; CAR-T cell administration, autologous.
J3490	J3490, J3590, or J9999 (Unclassified drugs or biologicals, TOS F), to be used: (1) when the dose of CAR T-cell therapy exceeds the code descriptor, or, (2) when other CAR T-cell therapy obtains FDA approval but have not yet received a specific HCPCS code.
J3590	
J9999	
Access Transmittal 11584 (CR 12822) and see worksheet (110.24), for ICD-10 diagnosis codes applicable to CPT codes above..	

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQC): Clinton White MD
Senior Medical Director: Jim Romero MD
Date Approved: 08/21/2024

References

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), (see Treatment by Cancer type) Accessed 05/21/2024.
2. Hayes, Axicabtagene Ciloleucel (Yescarta) for Treatment of Relapsed or Refractory B-Cell Malignancies, Precision Therapy Assessment Dec 11, 2022 | Annual Review: Jun 29, 2023. Accessed 05/21/2024
3. Hayes, (Tisagenlecleucel) for Diffuse Large B-Cell Lymphoma, Archived 12/12/2018. Accessed 05/21/2024
4. Hayes, Tisagenlecleucel (Kymriah) for Treatment of Relapsed or Refractory CD19+ B-Cell Malignancies, Precision Therapy Assessment, Jun 30, 2020 | Aug 31, 2021. [Accessed 05/21/2024]
5. Hayes, Abecma (Idecabtagene Vicleucel) for Multiple Myeloma, Emerging Technology, Report, Mar 29, 2021. [Cited 05/21/2024]
6. Hayes, Breyanzi (Lisocabtagene Maraleucel) for Large B-Cell Lymphoma, Emerging Technology Report, Apr 15, 2021 [Cited 05/21/2024]
7. CMS, MLN Matters, National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy, MLN Matters Number: MM12177, (Revised), Effective Date: August 7, 2019, Implementation Date: September 20, 2021. [Cited 05/21/2024].
8. CMS Manual System, Pub 100-03 Medicare National Coverage Determinations, (TN 11584) (CR12822), Date Aug 31, 2022. [Cited 05/21/2024]
9. (NCD) for CHIMERIC ANTIGEN RECEPTOR (CAR) T-cell Therapy (110.24), effective date: 08/07/2019, implementation date 09/20/2021 [Cited 05/21/2024]

Publication History

03-27-19:	Policy approved by CQUMC on 03/27/2019. Went before TAC 08/28/2018.
06-13-19:	Updated new HCPCS codes
07-22-20	Annual review. Reviewed by PHP Medical Policy Committee on 06/30/2020. Policy continues coverage for Medicare, Medicaid and Commercial, using NCCN guideline. Codes Q2041, Q2042, 0538T, 0539T and 0540T will now require PA. Codes Q2041/42 are on Pass-Through Payment list. Codes Q2043 and Q2049 were removed due to error.
07-28-21	Annual review. Reviewed by PHP Medical Policy Committee on 07/09/2021. Policy continues coverage for Medicare, Medicaid and Commercial. Policy will now follow (NCD 110.24) for Chimeric Antigen Receptor (CAR) T-cell Therapy for both existing and new drugs. Will also continue using REMS provided by FDA and NCCN guidelines. Criteria added for the following new drugs: (ABECMA® (for multiple myeloma); TECARTUS™ (for mantle cell lymphoma); and BREYANZI® (for large B-cell lymphoma and diffuse large B-cell lymphoma (DLBCL)) and their related CPT codes (Q2053, C9076 and C9399) added to policy, which will all require PA for all LOB. Added a list of primary ICD-10 in the policy from Transmittal R10796CP. *HCPCS code C9073 was deleted 04/01/2021 and to report, see Q2053.
07-27-22	Annual review. Reviewed by PHP Medical Policy Committee on 06-29-2022. Continue to follow NCD 100.24. The criteria for Yescarta, Kymriah, Tecartus and Breyanzi was updated per DailyMed Drug Label information. Codes updated per NCD 110.24 changes: New codes (Q2054 and Q2055, J3490, J3590 and J9999) added to policy which will be added to require prior authorization. Codes C9076 and C9399 were removed. The list of ICD-10 were removed and only the hyperlink to Transmittal 11391 (CR 12606) was provided.
07-26-23	Annual review. Reviewed by PHP Medical Policy Committee on 05/24/2023. The criteria has been removed and replaced to say we follow Optum, since we have been using Optum Car T-Cell Therapy Clinical Guidelines. Added code Q2056, effective 02/28/2022, which will require PA for ALOB.

08-21-24 Annual review. Reviewed by PHP Medical Policy Committee on 05/24/2024. Continue to use Optum. The transplant Optum team evaluates requests for CAR-T and PHP does not need to have the policy outline the criteria with drug information. The purchased criteria for Optum were reviewed on 05/22/2024. Continue PA requirement for: J3490, J9999, Q2041, Q2042, Q2053, Q2054, Q2055, Q2056, 0537T, 0538T, 0539T, 05340T for ALOB. NCD 110.24 has no update on codes per (TN 11584) (CR12822).

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.