Pharmacy Management Drug Policy

SUBJECT: Chimeric Antigen Receptor T Cell (CAR-T) Therapy
POLICY NUMBER: PHARMACY-103
EFFECTIVE DATE: 04/26/2022
LAST REVIEW DATE: 12/05/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Chimeric Antigen Receptor T Cell (CAR-T) therapy is a type of adoptive cellular therapy where T cells are engineered to detect and destroy diseased cells. There are seven (7) Food and Drug Administration (FDA) approved CAR-T therapies available for the treatment of hematological malignancies:

Trade Name	Chemical Name	Target	FDA Approved Indication(s)
Abecma	idecabtagene vicleucel	B-cell maturation antigen (BCMA)	• indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody
Aucatzyl	Obecabtagene autoleucel	CD19	• indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
Breyanzi	lisocabtagene maraleucel	CD19	• indicated for the treatment of adult patients with large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B who have: ○ refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first line chemoimmunotherapy ○ refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age ○ relapsed or refractory disease after two or more lines of systemic therapy • indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least two prior lines of therapy including, a bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.

			• Indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy • Indicated for the treatment of adult patients with relapsed or refractory mantel cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor • Indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least 2 prior lines of systemic therapy
Carvykti	ciltacabtagene autoleucel	B-cell maturation antigen (BCMA)	• indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least 1 prior line of therapy, including a proteasome inhibitor, and an immunomodulatory agent, and are refractory to lenalidomide.
Kymriah	tisagenlecleucel	CD19	• indicated for the 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 • indicated for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma • indicated for the treatment of adult patients with relapsed or refractory (r/r) follicular lymphoma (FL) after two or more lines of systemic therapy
Tecartus	brexucabtagene autoleucel	CD19	• indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) • indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
Yescarta	axicabtagene ciloleucel	CD19	• indicated for the 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 • indicated for the 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, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma • indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy

Prior Authorization criteria listed in this policy is based on FDA labeled indication or NCCN level of evidence 1 or 2A. For requests that do not meet the policy criteria defined below, please refer to the Off-Label Use of FDA Approved Drugs policy.

POLICY GUIDELINES:

1. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to approve language being added to the policy.
2. Supportive documentation of previous drug use must be submitted for any criteria which require trial of a preferred agent if the preferred drug is not found in claims history.

3. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options).
4. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
5. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
6. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient’s best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
7. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.
8. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
9. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-

Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.

10. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32). This includes any request that is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy.
11. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
12. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
13. Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies
    a. One-Time Administration
        i. Most gene and cellular therapies, whether autologous, allogeneic (“off-the-shelf”), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
        ii. Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.
    b. Retreatment/Repeat Administration
        i. Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
            a) Clinical trials evaluated these therapies as single-administration interventions
            b) Safety, efficacy, and durability of a second administration have not been established
            c) Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing
    c. Treatment with an Additional or Other Gene/Cellular Therapy
        i. Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is also considered experimental and investigational, unless supported by evidence demonstrating (a-d):
            a) Anticipated clinical benefit beyond available standard therapies
            b) Safety of sequential administration
            c) Justification for selecting a second gene/cellular intervention after a prior one
            d) Meets the criteria established in the Off-Label Use of FDA Approved Pharmacy Management Drug Policy (Pharmacy-32)
        ii. This includes, but is not limited to:
            a) Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
            b) Switching between autologous and allogeneic cellular therapies
            c) Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
            d) Receiving a gene therapy after previous gene or cellular therapy exposure
            e) Receiving an in vivo gene therapy following any prior vector-based therapy

d. Prior Gene/Cell Therapy Exposure
   i. An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
      a) Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
      b) Any allogeneic genetically modified cellular therapy,
      c) Any in vivo gene therapy (e.g., AAV, lentiviral vector)
      d) Any ex vivo gene-modified cell product
      e) Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.

e. Coverage Determination
   i. Absent peer-reviewed evidence demonstrating safety and benefit, retreatment or sequential therapy is considered investigational and will not be covered.

APPROVAL TIME PERIODS

Line of Business	Approval timeframe
Commercial, Exchange, and SafetyNet (Medicaid, HARP, CHP, Essential Plan)	6 months
Medicare	6 months

CURRENT CAR-T THERAPIES:

DRUG NAME (Medical benefit)
Authorization Criteria
Abecma (idecabtagene vicleucel) - Medical
1. Must be prescribed by a Hematologist or Oncologist **AND** 2. Must be ≥ 18 years of age **AND** 3. Must have a diagnosis of **relapsed or refractory multiple myeloma AND** 4. Must have measurable disease, defined as having at least one of the following: a. Serum M-protein greater or equal to 1.0 g/dL **OR** b. Urine M-protein greater or equal to 200 mg/24 h **OR** c. Serum free light chain (FLC) assay: involved FLC level greater or equal to 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal **AND** 5. Must have received at least 2 prior lines of therapies including an anti-CD38 monoclonal antibody (daratumumab, isatuximab-irfc), a proteasome inhibitor (bortezomib, carfilzomib, ixazomib), **AND** an immunomodulatory agent (lenalidomide, pomalidomide) **AND** 6. Patients approved for Abecma will also receive approval of tocilizumab for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer tocilizumab as either 12 mg/kg IV over 1 hour for patients < 30kg or 8 mg/kg IV over 1 hour for patients ≥ 30kg 7. Prior authorization for Abecma will apply regardless of the site of administration (applies to both the inpatient and outpatient setting) **HCPCS**: Q2055
Aucatzyl (obecabtagene autoleucel) - Medical
1. Must be prescribed by a Hematologist or Oncologist **AND** 2. Must be ≥ 18 years of age **AND** 3. Must meet the following: a. Must have a diagnosis of relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) with morphological disease in the bone marrow (> 5% blasts) **AND** i. Must have relapsed or refractory disease defined as:

a) Must be refractory to 2 or more lines of systemic therapy **OR**
b) In first relapse, with remission of 12 months or less **OR**
c) Must have had bone marrow relapse after allogeneic stem cell transplant (HSCT) **OR**
d) Must have primary refractory disease (having less than a complete response [CR] after initial induction therapy) **AND**

ii. Patient has Philadelphia Chromosome negative ALL, **OR**
iii. Patient has Philadelphia chromosome positive (Ph+) disease **AND**
a) Patient has failed two prior lines of any TKI; **OR**
b) Patient has failed one prior line of second generation TKI; **OR**
c) Patient has a contraindication to TKIs

4. Must not have central nervous system involvement **AND**
5. Must not have received prior anti-CD19 therapy other than blinatumomab.
6. Patients approved for Aucatzyl will also receive approval of tocilizumab for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer tocilizumab as either 12 mg/kg IV over 1 hour for patients < 30kg or 8 mg/kg IV over 1 hour for patients ≥ 30kg.
7. Prior authorization for Aucatzyl will apply regardless of the site of administration (applies to both the inpatient and outpatient setting).

HCPCS: Q2058

Breyanzi (lisocabtagene maraleucel) - Medical

1. Must be prescribed by a Hematologist or Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must meet one of the following:
   a. Must have a diagnosis of **large B-cell lymphoma** including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B **AND**
      i. Must meet one of the following:
         a) Must be used for relapsed or refractory disease after two or more lines of systemic therapy
            I. Must have received previous treatment with BOTH an anthracycline and a CD20-targeted agent (e.g., a rituximab containing product) **OR**
         b) Must be used for disease that is refractory to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy
            I. Must have received previous treatment with BOTH an anthracycline and a CD20-targeted agent (e.g., a rituximab containing product) **OR**
         c) Must be used for disease that is refractory to first-line line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
            I. Must have received previous treatment with BOTH an anthracycline and a CD20-targeted agent (e.g., a rituximab containing product) **AND**
      ii. Must have biopsy confirmed CD19-positive disease post-treatment with prior CD19-targeted therapy **OR** must not have been previously treated with CD19-targeted therapy **OR**
   b. Must have a diagnosis of **chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) AND**
      i. Must be used for relapsed or refractory disease after two or more lines of systemic therapy
         a) Must have received previous treatment with BOTH a BTK inhibitor (e.g., acalabrutinib, ibrutinib, etc.) and a BCL-2 inhibitor (e.g., venetoclax, etc.) **AND**
         b) Must have one or more indication(s) for treatment defined as:
            I. Significant disease-related symptoms:

1. Fatigue (severe) **OR**
2. Drenching night sweats **OR**
3. Unintentional weight loss (≥ 10% in previous 6 months) **OR**
4. Fever without infection **OR**

II. Threatened end-organ function **OR**
III. Progressive, symptomatic, or bulky disease (spleen >6 cm below costal margin, lymph nodes >10cm) **OR**
IV. Progressive thrombocytopenia **OR**
V. Progressive anemia **OR**
VI. Steroid-refractory autoimmune cytopenias **OR**

c. Must have a diagnosis of **relapsed or refractory follicular lymphoma (FL); AND**
   i. Must have grade 1,2, or 3A FL; **AND**
   ii. Must have one or more indication(s) for treatment defined as:
      a) Involvement of ≥ 3 nodal sites, each with a diameter of ≥ 3 cm; **OR**
      b) Any nodal or extranodal tumor mass with a diameter of ≥ 7 cm: **OR**
      c) B symptoms; **OR**
      d) Splenomegaly; **OR**
      e) Pleural effusions or peritoneal ascites; **OR**
      f) Cytopenias (leukocytes < 1.0 x 10^9/L and /or platelets <100 x 10^9/L); **OR**
      g) Leukemia (>5.0 x 10^9/L malignant cells); **AND**
   iii. Must be used after two or more lines of systemic therapy including all the following:
      a) A CD20-targeted agent (e.g., a rituximab containing product); **AND**
      b) An alkylating agent **OR**

d. Must have a diagnosis of **relapsed or refractory mantel cell lymphoma (MCL) AND**
   i. Must have received two or more lines of systemic therapy including all the following:
      a) A CD20-targeted agent (e.g., a rituximab containing product) **AND**
      b) An alkylating agent **AND**
      c) A bruton tyrosine kinase (BTK) inhibitor (such as acalabrutinib [Calquence], zanubrutinib [Brukinsa], etc) **OR**

e. Must have a diagnosis of **relapsed or refractory marginal zone lymphoma (MZL) AND**
   i. Must have received at least two or more lines of systemic therapy including all the following:
      a) A CD20-targeted agent (e.g., a rituximab containing product) **AND**
      b) An alkylating agent **AND**

4. Breyanzi will not be approved for a diagnosis of primary central nervous system lymphoma
5. Patients approved for Breyanzi will also receive approval of tocilizumab for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer tocilizumab as either 12 mg/kg IV over 1 hour for patients < 30kg or 8 mg/kg IV over 1 hour for patients ≥ 30kg
6. Prior authorization for Breyanzi will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

HCPCS: Q2054

Carvykti (ciltacabtagene autoleucel) - Medical

1. Must be prescribed by a Hematologist or Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of **relapsed or refractory multiple myeloma AND**
4. Must have measurable disease, defined as having at least one of the following:
   a. Serum M-protein greater or equal to 1.0 g/dL **OR**
   b. Urine M-protein greater or equal to 200 mg/24 h **OR**
   c. Serum free light chain (FLC) assay: involved FLC level greater or equal to 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal **AND**

5. Must have received at least 1 prior line of therapy including a proteasome inhibitor (bortezomib, carfilzomib, ixazomib), an immunomodulatory agent (lenalidomide, pomalidomide) **AND** must be refractory to lenalidomide **AND**
6. Patients approved for Carvykti will also receive approval of tocilizumab for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer tocilizumab as either 12 mg/kg IV over 1 hour for patients < 30kg or 8 mg/kg IV over 1 hour for patients ≥ 30kg
7. Prior authorization for Carvykti will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

HCPCS: Q2056

Kymriah (tisagenlecleucel) - Medical

1. Must be prescribed by a Hematologist or Oncologist **AND**
2. Must have meet one of the following:
   a. Must have a diagnosis of **CD19-positive B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)** with morphological disease in the bone marrow (> 5% blasts) **AND**
      i. Must be ≤ 25 years of age **AND**
      ii. Must have refractory disease, be in second or later bone marrow relapse, or have bone marrow relapse after allogenic stem cell transplant
         1. Members with Philadelphia chromosome positive B-ALL must have relapsed/refractory disease despite treatment with at least 2 different tyrosine kinase inhibitors (TKI) [Sprycel (dasatinib), Gleevec (imatinib), Iclusig (ponatinib), Tasigna (nilotinib), Bosulif (bosutinib)] unless treatment with a TKI is contraindicated **OR**
   b. Must have a diagnosis of **relapsed or refractory large B-cell lymphoma** including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma **AND**
      i. Must be 18 years of age or older **AND**
      ii. Must be used after two or more lines of systemic therapy
         1. Must have received previous treatment with BOTH an anthracycline and a CD20-targeted agent (e.g., a rituximab containing product) **OR**
   c. Must have a diagnosis of **relapsed or refractory follicular lymphoma (FL)**
      i. Must be 18 years of age or older **AND**
      ii. Must have grade 1,2, or 3A FL **AND**
      iii. Must have one or more indication(s) for treatment defined as:
         1. Involvement of ≥ 3 nodal sites, each with a diameter of ≥ 3 cm
         2. Any nodal or extranodal tumor mass with a diameter of ≥ 7 cm
         3. B symptoms
         4. Splenomegaly
         5. Pleural effusions or peritoneal ascites
         6. Cytopenias (leukocytes < 1.0×10^9/L and/or platelets < 100×10^9/L)
         7. Leukemia (> 5.0×10^9/L malignant cells); **AND**
      iv. Must have had at least 2 lines of systemic therapy or an autologous hematopoietic stem cell transplant (HSCT)
3. Kymriah will not be approved for a diagnosis of primary central nervous system lymphoma
4. Patients approved for Kymriah will also receive approval of tocilizumab for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer tocilizumab as either 12 mg/kg IV over 1 hour for patients < 30kg or 8 mg/kg IV over 1 hour for patients ≥ 30kg
5. Prior authorization for Kymriah will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

HCPCS: Q2042

Tecartus (brexucabtagene autoleucel) - Medical

1. Must be prescribed by a Hematologist or Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must meet one of the following:
   a. Must have a diagnosis of **relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL)** with morphological disease in the bone marrow (> 5% blasts) **AND**
      i. Must have relapsed or refractory disease defined as:
         1. Must be refractory to 2 or more lines of systemic therapy **OR**
         2. In first relapse, with remission of 12 months or less **OR**
         3. Must have had bone marrow relapse after allogeneic stem cell transplant (HSCT) **OR**
         4. Must have primary refractory disease (having less than a complete response [CR] after initial induction therapy) **AND**
      ii. Patients with Philadelphia chromosome positive (Ph+) disease must have had relapsed/refractory disease despite treatment with at least 2 different tyrosine kinase inhibitors (TKI) unless treatment with a TKI is contraindicated **OR**
   b. Must have a diagnosis **relapsed or refractory mantel cell lymphoma AND**
      i. Must have at least 1 measurable lesion **AND**
      ii. Must have had previous treatment with all the following:
         1. A CD20-targeted agent (e.g., a rituximab containing product) **AND**
         2. Anthracycline or bendamustine-containing chemotherapy **AND**
         3. A bruton tyrosine kinase (BTK) inhibitor (such as ibrutinib [Imbruvica], and acalabrutinib [Calquence])
4. Patients approved for Tecartus will also receive approval of tocilizumab for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer tocilizumab as either 12 mg/kg IV over 1 hour for patients < 30kg or 8 mg/kg IV over 1 hour for patients ≥ 30kg
5. Prior authorization for Tecartus will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

HCPCS: Q2053

Yescarta (axicabtagene ciloleucel) - Medical

1. Must be prescribed by a Hematologist or Oncologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must meet one of the following:
   a. Must have a diagnosis of **relapsed or refractory Follicular Lymphoma (FL)**
      i. Must have grade 1,2, or 3A FL
      ii. Must have one or more indication(s) for treatment defined as:
         1. Involvement of ≥ 3 nodal sites, each with a diameter of ≥ 3 cm
         2. Any nodal or extranodal tumor mass with a diameter of ≥ 7 cm
         3. B symptoms
         4. Splenomegaly
         5. Pleural effusions or peritoneal ascites
         6. Cytopenias (leukocytes < 1.0×10^9/L and/or platelets < 100×10^9/L)
         7. Leukemia (> 5.0×10^9/L malignant cells)
      iii. Must be used after two or more prior chemoimmunotherapy regimens
         1. One regimen must include a CD20-targeted agent (e.g., a rituximab containing product) in combination with an alkylating agent **OR**
   b. Must be used as third-line therapy for a diagnosis of **relapsed or refractory large B-cell lymphoma** including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary

mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma
   i. Must have received previous treatment with BOTH an anthracycline and a CD20-targeted agent (e.g., a rituximab containing product) **OR**
c. Must be used as second-line therapy for a diagnosis of **primary refractory (defined as no complete remission to first-line therapy) or relapsed (defined as complete remission to first-line therapy followed by biopsy-proven relapse ≤ 12 months of first-line therapy) large B-cell lymphoma** (see ZUMA-7 inclusion criteria)
   i. Must have received adequate first-line therapy including an anthracycline and a CD20-targeted agent (e.g., a rituximab containing product)
4. Yescarta will not be approved for a diagnosis of primary central nervous system lymphoma
5. Patients approved for Yescarta will also receive approval of tocilizumab for a period of 6 months. If severe or life-threatening cytokine-release syndrome is suspected (CRS), administer tocilizumab as either 12mg/kg IV over 1 hour for patients <30kg or 8mg/kg IV over 1 hour for patients ≥30kg
6. Prior authorization for Yescarta will apply regardless of the site of administration (applies to both the inpatient and outpatient setting)

HCPCS: Q2041

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. Codes may not be covered under all circumstances.

Please read the policy and guidelines statements carefully.
Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

HCPCS:

Trade Name	Chemical Name	HCPCS
Abecma	idecabtagene vicleucel	Q2055
Aucayzyl	obecabtagene autoleucel	Q2058
Breyanzi	lisocabtagene maraleucel	Q2054
Carvykti	ciltacabtagene autoleucel	Q2056
Kymriah	tisagenlecleucel	Q2042
Tecartus	brexucabtagene autoleucel	Q2053
Yescarta	axicabtagene ciloleucel	Q2041

IMPORTANT INFORMATION ON ACCELERATED APPROVAL:

Refer to the following FDA websites for up-to-date information on ongoing, verified, and withdrawn accelerated approval indications:

Ongoing Cancer Accelerated Approvals:
https://www.fda.gov/drugs/resources-information-approved-drugs/ongoing-cancer-accelerated-approvals

Verified Clinical Benefit Cancer Accelerated Approvals:
https://www.fda.gov/drugs/resources-information-approved-drugs/verified-clinical-benefit-cancer-accelerated-approvals

Withdrawn Cancer Accelerated Approvals:*
https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals

*Note: Individuals currently receiving treatment for a withdrawn indication should consult with their healthcare practitioner whether to remain on treatment. Coverage of a treatment with a withdrawn indication will only be considered should the patient be established on therapy prior to the withdrawal date listed on the FDA website.

UPDATES:

Date	Revision
12/05/2025	Revised
12/03/2025	Revised
11/19/2025	Revised
07/07/2025	Revised
05/21/2025	Revised
05/08/2025	Reviewed / P&T Committee Approval
03/06/2025	Revised
02/19/2025	Revised
02/03/2025	Revised
12/19/2024	Revised
09/13/2024	Revised
06/24/2024	Revised
05/09/2024	P&T Committee Approval
04/24/2024	Revised
04/05/2024	Revised
03/25/2024	Revised
5/11/2023	P&T Committee Approval
11/2022	Revised
05/2022	P&T Committee Approval
04/2022	Created

REFERENCES:

In addition to the full prescribing information for each individual drug and NCCN Drugs and Biologic Compendium, the following references have been utilized in creating drug specific criteria

1. Maciocia PM, Maciocia NC, Pule MA. Immune Cell Therapy: Chimeric Antigen Receptor T-Cell Therapy. In: Kaushansky K, Prchal JT, Burns LJ, Lichtman MA, Levi M, Linch DC. eds. Williams Hematology, 10e. McGraw Hill; 2021.