To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

Table of Contents

1.0 Description of the Procedure, Product, or Service ............................................................... 1
  1.1 Definitions .......................................................................................................................... 2
     1.1.1 Rescue Transplant .................................................................................................. 2

2.0 Eligibility Requirements ........................................................................................................ 2
  2.1 Provisions ........................................................................................................................ 2
     2.1.1 General ................................................................................................................... 2
     2.1.2 Specific .................................................................................................................. 2
  2.2 Special Provisions ............................................................................................................. 2
     2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age ................................................................. 2
     2.2.2 EPSDT does not apply to NCHC beneficiaries ..................................................... 4
     2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age ........................................................................................................... 4

3.0 When the Procedure, Product, or Service Is Covered ............................................................ 4
  3.1 General Criteria Covered .................................................................................................. 4
  3.2 Specific Criteria Covered .................................................................................................. 4
     3.2.1 Specific criteria covered by both Medicaid and NCHC ........................................ 4
     3.2.2 Medicaid Additional Criteria Covered ................................................................... 6
     3.2.3 NCHC Additional Criteria Covered ...................................................................... 6

4.0 When the Procedure, Product, or Service Is Not Covered .................................................... 7
  4.1 General Criteria Not Covered ............................................................................................ 7
  4.2 Specific Criteria Not Covered ............................................................................................ 7
     4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC .................................. 7
     4.2.2 Medicaid and NCHC Additional Criteria Not Covered ......................................... 8
     4.2.3 Psychosocial History .............................................................................................. 8
     4.2.4 Medical Compliance .............................................................................................. 8
     4.2.5 Medicaid Additional Criteria Not Covered ............................................................ 8
     4.2.6 NCHC Additional Criteria Not Covered ................................................................ 8

5.0 Requirements for and Limitations on Coverage ................................................................. 8
  5.1 Prior Approval ................................................................................................................... 8
  5.2 Prior Approval Requirements ............................................................................................ 8
     5.2.1 General ................................................................................................................... 8
     5.2.2 Specific .................................................................................................................. 9
  5.3 Additional Limitations or Requirements ........................................................................... 9

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service ....................................... 9
  6.1 Provider Qualifications and Occupational Licensing Entity Regulations .......................... 9
  6.2 Provider Certifications ..................................................................................................... 10
7.0 Additional Requirements .................................................................................................................. 10
7.1 Compliance ......................................................................................................................................... 10

8.0 Policy Implementation and History ..................................................................................................... 11

Attachment A: Claims-Related Information .......................................................................................... 12
A. Claim Type ............................................................................................................................................. 12
B. International Classification of Diseases and Related Health Problems, Tenth Revisions,
   Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) ................................12
C. Code(s) ................................................................................................................................................ 13
D. Modifiers............................................................................................................................................... 13
E. Billing Units......................................................................................................................................... 14
F. Place of Service ................................................................................................................................. 14
G. Co-payments ...................................................................................................................................... 14
H. Reimbursement ................................................................................................................................. 14
1.0 Description of the Procedure, Product, or Service

Engineered T cell–based antitumor immunotherapy uses gene transfer of tumor antigen-specific T-cell receptors (TCR) or synthetic chimeric antigen receptors (CAR-T). CAR-T cells are prepared from the patient’s peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. The blood is sent to the manufacturer where the mononuclear cells are enriched for T cells. The T cells are expanded in cell culture, washed, and formulated into a suspension, which then is cryopreserved. This process may take several weeks. The product is then infused into the patient. This technique has shown very encouraging results in clinical trials for treatment of types of leukemias and lymphomas.

Tisagenlecleucel (KYMRIAH) is a CD19-directed genetically modified autologous T cell immunotherapy. Each dose is a customized treatment created using an individual’s own T-cells. The individual’s T-cells are collected and sent to a manufacturing center where they are genetically modified to include a new gene that contains a specific protein (a chimeric antigen receptor or CAR) that directs the T-cells to target and kill leukemia cells that have a specific antigen (CD19) on the surface. Once the cells are modified, they are infused back into the individual. Upon binding to the CD19-expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, target cell elimination and persistence of the KYMRIAH cells.

Axicabtagene ciloleucel (YESCARTA) is a CD19-directed genetically modified autologous T cell immunotherapy. To prepare the product an individual’s own T cells are harvested and genetically modified ex vivo by retroviral transduction to express a chimeric antigen receptor (CAR) comprising a murine anti-CD19 single chain variable fragment (scFv) linked to CD28 and CD3-zeta co-stimulatory domains. The anti-CD19 CAR T cells are expanded and infused back into the individual. Axicabtagene ciloleucel binds to CD19-expressing cancer cells and normal B cells. Studies demonstrated that following anti-CD19 CAR T cell engagement with CD19-expressing target cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.
1.1 Definitions

1.1.1 Rescue Transplant
A method of replacing blood-forming stem cells that were destroyed by treatment with high doses of anticancer drugs or radiation therapy. The stem cells help the bone marrow recover and make healthy blood cells. A rescue transplant may allow more chemotherapy or radiation therapy to be given so that more cancer cells are killed. It is usually done using the patient’s own stem cells that were saved before treatment. Also called stem cell rescue.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General
(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
   2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in Section 3.0 of this policy.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary’s eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific
(The term “Specific” found throughout this policy only applies to this policy)

a. Medicaid
   None Apply.

b. NCHC
   None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]
   Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health
problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary’s physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary’s right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider’s documentation shows that the requested service is medically necessary “to correct or ameliorate a defect, physical or mental illness, or a condition” [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.

2. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/
2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within Section 3.0 of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary’s needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary’s caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

a. Medicaid and NCHC shall cover tisagenlecleucel (KYMRIAH) for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) when ALL of the following criteria are met:

1. Medicaid beneficiary is 25 years of age or younger; or NCHC beneficiary between the ages of 6 through 18;

2. beneficiary has CD19-positive disease;

3. disease is refractory or in relapse as exhibited by ANY ONE of the following:
   A. second or greater bone marrow relapse;
   B. any bone marrow relapse after allogeneic stem cell transplantation;
   C. primary refractory (not achieving a complete response after two cycles of standard chemotherapy);
   D. chemorefractory (not achieving a complete response after one cycle of standard chemotherapy for relapsed disease);
   E. if disease is Philadelphia chromosome, failure of two tyrosine kinase inhibitors (imatinib, dasatinib, nilotinib, bosutinib) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; or
   F. the beneficiary is not eligible for allogenic stem cell transplantation;
4. performance score on Karnofsky or Lansky Scale is greater than or equal to 50% or Eastern Cooperative Oncology Group (ECOG) performance score is 0-3;
5. life expectancy greater than 12 weeks;
6. used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy);
7. prophylaxis for infection has been followed according to local guidelines;
8. the beneficiary has been screened for hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) prior to collection of cells (leukapheresis);
9. the beneficiary has not received live vaccines within six weeks prior to the start of lymphodepleting chemotherapy and during treatment with tisagenlecleucel must not receive live vaccines until immune recovery following treatment; and
10. healthcare facility has enrolled in the KYMRIAH Risk Evaluation and Mitigation Strategies (REMS) and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities (see Section 6.2 for the required components of the KYMRIAH REMS).

b. Medicaid and NCHC shall cover tisagenlecleucel (KYMRIAH) for the treatment of adult patients with relapsed or refractory large B-cell lymphoma when ALL of the following criteria are met:
1. Medicaid beneficiary is 18 years of age or older; or NCHC beneficiary is 18 years old;
2. beneficiary has CD19-positive disease;
3. disease is ANY ONE of the following:
   A. diffuse large B-cell lymphoma not otherwise specified;
   B. diffuse large B-cell lymphoma arising from follicular lymphoma; or
   C. high grade B-cell lymphoma;
4. disease is relapsed or refractory after two or more lines of systemic therapy including rituximab and anthracycline, and either having failed autologous hematopoietic stem cell transplantation (ASCT), or being ineligible for ASCT;
5. performance score on Karnofsky or Lansky Scale is greater than or equal to 50% or Eastern Cooperative Oncology Group (ECOG) performance status of 0-1;
6. life expectancy greater than 12 weeks;
7. used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy);
8. prophylaxis for infection has been followed according to local guidelines;
9. the beneficiary has been screened for hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) prior to collection of cells (leukapheresis);
10. the beneficiary has not received live vaccines within six weeks prior to the start of lymphodepleting chemotherapy and during treatment with tisagenlecleucel must not receive live vaccines until immune recovery following treatment; and
11. healthcare facility has enrolled in the KYMRIAH Risk Evaluation and Mitigation Strategies (REMS) and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities (see Section 6.2 for the required components of the KYMRIAH REMS).

c. Medicaid and NCHC shall cover axicabtagene ciloleucel (YESCARTA) for the treatment of large B-cell lymphoma when ALL of the following criteria are met:
1. Medicaid beneficiary is 18 years of age or older; or NCHC beneficiary is 18 years old;
2. beneficiary has CD19-positive disease;
3. disease is ANY ONE of the following:
   D. diffuse large B-cell lymphoma (DLBCL), not otherwise specified;
   E. diffuse large B-cell lymphoma arising from follicular lymphoma;
   F. primary mediastinal large B-cell lymphoma; or
   G. high grade B-cell lymphoma;
4. disease is relapsed or refractory after two or more lines of systemic therapy (prior systemic therapy must have included anthracycline as well as an anti-CD20 monoclonal antibody [unless tumor is CD20-negative]
   NOTE: relapsed defined as within one year after autologous hematopoietic stem cell transplantation, or refractory disease to most recent therapy);
5. performance score on Karnofsky or Lansky Scale is greater than or equal to 50% or Eastern Cooperative Oncology Group (ECOG) performance status of 0-1;
6. the beneficiary has been screened for hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) prior to collection of cells (leukapheresis);
7. the beneficiary has not received live vaccines within six weeks prior to the start of lymphodepleting chemotherapy and during treatment with axicabtagene ciloleucel must not receive live vaccines until immune recovery following treatment; and
8. the healthcare facility has enrolled in the YESCARTA Risk Evaluation and Mitigation Strategies (REMS) and training has been given to providers on the management of cytokine release syndrome and neurological toxicities (see Section 6.2 for the required components of the YESCARTA REMS).

3.2.2 Medicaid Additional Criteria Covered
None Apply.

3.2.3 NCHC Additional Criteria Covered
None Apply.
4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in Section 2.0;

b. the beneficiary does not meet the criteria listed in Section 3.0;

c. the procedure, product, or service duplicates another provider’s procedure, product, or service; or

d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

a. Medicaid and NCHC shall not cover tisagenlecleucel (KYMRIAH) for ANY one of the following:
   1. the treatment of other conditions or diseases not covered in Subsection 3.2.1 of this policy;
   2. use as first-line therapy for ALL;
   3. use as first-line therapy for large B-cell lymphoma;
   4. beneficiaries with primary central nervous system (CNS) lymphoma;
   5. repeat treatment in beneficiaries who have received tisagenlecleucel or another CAR-T cell treatment previously;
   6. pregnant or lactating women; or
   7. beneficiaries with ANY one of the following:
      A. active infection;
      B. hepatitis B virus, hepatitis C virus or human immunodeficiency virus;
      C. inflammatory disorders; or
      D. prior allogenic hematopoietic stem cell transplantation for diagnoses of large B-cell lymphoma.

b. Medicaid and NCHC shall not cover axicabtagene ciloleucel (YESCARTA) for ANY one of the following:
   1. the treatment of other conditions or diseases not covered in Subsection 3.2.1 of this policy;
   2. use as first-line therapy for large B-cell lymphoma;
   3. any central nervous system (CNS) disease (for example, brain metastases, CNS lymphoma, and a history or presence of CNS disorders such as seizure disorder, cerebrovascular ischemia or hemorrhage, dementia, cerebellar disease, or autoimmune disease with CNS involvement);
   4. repeat treatment in beneficiaries who have received axicabtagene ciloleucel or another CAR-T cell therapy previously;
   5. pregnant or lactating women;
   6. beneficiaries with ANY one of the following:
A. active infection;
B. hepatitis B virus, hepatitis C virus or human immunodeficiency virus;
C. inflammatory disorders; or
D. prior allogenic hematopoietic stem cell transplantation.

4.2.2 Medicaid and NCHC Additional Criteria Not Covered
Medicaid and NCHC shall not cover concurrent rescue transplant with infusion of tisagenlecleucel (KYMRIAH) or axicabtagene ciloleucel (YESCARTA) as this is considered experimental.

4.2.3 Psychosocial History
Medicaid and NCHC shall not cover CAR-T Cell Therapy when the beneficiary’s psychosocial history limits the beneficiary’s ability to comply with pre- and post-infusion medical care.

4.2.4 Medical Compliance
Medicaid and NCHC shall not cover CAR-T Cell Therapy when there is current beneficiary or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

4.2.5 Medicaid Additional Criteria Not Covered
None Apply.

4.2.6 NCHC Additional Criteria Not Covered
a. NCGS § 108A-70.21(b) “Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
1. No services for long-term care.
2. No nonemergency medical transportation.
3. No EPSDT.
4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection.”

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval
Medicaid and NCHC shall require prior approval for CAR-T Cell Therapy. The provider shall obtain prior approval before rendering CAR-T Cell Therapy.

5.2 Prior Approval Requirements

5.2.1 General
The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:
a. the prior approval request; and
b. all health records and any other records that support the beneficiary has met
the specific criteria in Subsection 3.2 of this policy.

5.2.2 Specific

The provider(s) shall submit the following to the NC Medicaid nurse consultant:

a. Letter of medical necessity signed by the attending physician, which
documents past chemotherapy regimens and dates, the clinical and social
history, and indications for treatment with CAR-T cell therapy;

b. Copy of contract between administering facility and manufacturer of the
requested CAR-T cell therapy;

c. Serologies (less than three months old) to include Human Immunodeficiency
Virus (HIV) and Hepatitis panel. (Positive serology results may be reported
that are greater than three months old);

d. All diagnostic and procedure results, including bone marrow aspiration (not
more than six months old);

e. Complete psychological and social evaluation to include:
   1. beneficiary’s medical compliance;
   2. beneficiary’s support network;
   3. post-treatment care plan, with identification of primary and secondary
care providers; and
   4. history of mental health issues, substance use, or legal issues.

5.3 Additional Limitations or Requirements

The provider shall submit documentation of 30-day patient response to tisagenlecleucel
(KYMRIAH) as a follow-up to the prior approval request. This documentation must be
attached with claim submission. Medicaid and NCHC shall not pay any billed
KYMRIAH charge until after all data regarding the 30-day patient response is received
and reviewed.

The provider shall submit documentation of 30-day patient response to axicabtagene
ciloleucel (YESCARTA) as a follow-up to the prior approval request. This
documentation must be attached with claim submission. Medicaid and NCHC shall
not pay any billed YESCARTA charge until after all data regarding the 30-day patient
response is received and reviewed.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s)
shall:

a. meet Medicaid or NCHC qualifications for participation;

b. have a current and signed Department of Health and Human Services (DHHS) Provider
Administrative Participation Agreement; and

c. bill only for procedures, products, and services that are within the scope of their clinical
practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.
6.2 Provider Certifications

a. Because of the risk of CRS and neurological toxicities, KYMRIAH is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS. The required components of the KYMRIAH REMS are:
   1. Healthcare facilities that dispense and administer KYMRIAH must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for administration within two hours after KYMRIAH infusion, if needed for treatment of CRS;
   2. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer KYMRIAH are trained about the management of CRS and neurological toxicities.

b. Because of the risk of CRS and neurological toxicities, YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA REMS. The required components of the YESCARTA REMS are:
   1. Healthcare facilities that dispense and administer YESCARTA must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within two hours after YESCARTA infusion, if needed for treatment of CRS;
   2. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer YESCARTA are trained about the management of CRS and neurological toxicities.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).
8.0 Policy Implementation and History

Original Effective Date: December 1, 2019

History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Section or Subsection Amended</th>
<th>Change</th>
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<tbody>
<tr>
<td>12/01/2019</td>
<td>All Sections and Attachment(s)</td>
<td>New Clinical Coverage Policy documenting criteria for CAR-T Cell Therapy involving the administration of tisagenlecleucel (KYMRIAH) and axicabtagene ciloleucel (YESCARTA).</td>
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<tr>
<td>12/01/2019</td>
<td>Attachment A</td>
<td>Updated policy template language “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.</td>
</tr>
<tr>
<td>12/01/2019</td>
<td>Table of Contents</td>
<td>Updated policy template language, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.”</td>
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Attachment A: Claims-Related Information

Provider(s) shall comply with the, NCTracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Institutional (UB-04/837I)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

<table>
<thead>
<tr>
<th>ICD-10-CM Code(s)</th>
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<td>KYMRIAH</td>
<td>YESCARTA</td>
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a. Provider(s) shall file inpatient claims for CAR-T Cell Therapy with ICD-10 PCS XW033C3 or XW043C3.

b. Provider(s) shall include the prior authorization (PA) number on the claim.

c. Provider(s) shall attach documentation with the claim regarding 30-day patient response and invoice from manufacturer of CAR-T Cell Therapy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

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<th>HCPCS Code(s)</th>
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<tbody>
<tr>
<td>Q2042 (KYMRIAH)</td>
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<tr>
<td>Q2041 (YESCARTA)</td>
</tr>
</tbody>
</table>

a. Provider(s) shall file outpatient claims for CAR-T Cell Therapy with Revenue Code 0636 and HCPCS Q2042 (KYMRIAH) or Q2041 (YESCARTA).

b. Provider(s) shall include the prior authorization (PA) number on the claim.

c. Provider(s) shall attach documentation with the claim regarding 30-day patient response and invoice from manufacturer of CAR-T Cell Therapy.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions for Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

Provider(s) billing for 340B drugs shall bill the cost that is reflective of their acquisition cost.
Provider(s) shall indicate that a drug was purchased under a 340B purchasing agreement by appending the “UD” modifier on the drug detail.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

Providers must bill National Drug Codes (NDCs) and appropriate NDC units.

<table>
<thead>
<tr>
<th>KYMRIAH</th>
<th>YESCARTA</th>
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<tbody>
<tr>
<td>Ped ALL: NDC 0078-0846-19</td>
<td>NDC 71287-119-01 (infusion bag)</td>
</tr>
<tr>
<td>DLBCL: NDC 0078-0958-19</td>
<td>NDC 71287-119-02 (metal cassette)</td>
</tr>
</tbody>
</table>

The NDC units must be reported as “UN1.”

F. Place of Service

Inpatient Hospital, Outpatient Hospital.

G. Co-payments


H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/