KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

Coding and Billing Guide for KYMRIAH

YOUR RESOURCE FOR CODING, BILLING, AND REIMBURSEMENT INFORMATION

Indications

KYMRIAH is a CD19-directed genetically modified autologous T cell immunotherapy 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
- 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

  Limitation of Use: KYMRIAH is not indicated for treatment of patients with primary central nervous system lymphoma.
- Adult patients with r/r follicular lymphoma (FL) after two or more lines of systemic therapy

  This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Important Safety Information for KYMRIAH® (tisagenlecleucel)

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGICAL TOXICITIES, and SECONDARY HEMATOLOGICAL MALIGNANCIES

- **Cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving KYMRIAH. Do not administer KYMRIAH to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids**
- **Neurological toxicities, including severe or life-threatening reactions, occurred following treatment with KYMRIAH, including concurrently with CRS. Monitor for neurological events after treatment with KYMRIAH. Provide supportive care and/or corticosteroids as needed**
- **T cell malignancies have occurred following treatment of hematological malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including KYMRIAH**

The coding information provided in this guide is gathered from various resources, is general in nature, and is subject to change without notice. Third-party payment for medical products and services is affected by many factors. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes, and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient. The provider is responsible for determining the appropriate health care setting and submitting accurate claims for products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information provided should in no way be considered a guarantee of coverage or reimbursement for any product or service.

While Novartis has identified a list of general codes, coding determinations are at the discretion of the provider and should be made in accordance with applicable regulations and payer guidance.

The information contained in this guide is not intended to provide legal advice of any kind.

Information provided in this guide is effective as of March, 2026.

Please see additional Important Safety Information on pages 21-23.

Click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

TABLE OF CONTENTS

1 SECTION 1: INTRODUCTION

This guide provides general coding and billing information to assist you with understanding the reimbursement of KYMRIAH following administration at one of the KYMRIAH Treatment Centers. The site of care should be determined by the health care provider (HCP) and the patient.

Depending on the site of service where KYMRIAH is administered and the type of payer, providers may be required to use different types of codes on their claims. Medicare and Medicaid typically use a diagnosis-related group (DRG)-based payment methodology for inpatient billing, but some states may use alternate methodologies. The code sets on the following pages are generally used by payers in the inpatient and outpatient settings.

Please refer to specific payer and state guidelines for direction on appropriate code selection.

Upon request, **KYMRIAH CARES™** will provide insurance benefits verification, including information on denials and appeals. **KYMRIAH CARES** is available Monday through Friday, 8:00 AM to 8:00 PM ET, at **1-844-4KYMRIAH** (1-844-459-6742).

Inpatient Setting

In the hospital inpatient setting, KYMRIAH, like most drugs and biologics, is not paid for separately but included in a bundled payment amount that covers the inpatient stay. Medicare, the majority of Medicaid plans, and many commercial payers use a diagnosis-related group, or DRG, based grouping methodology, which assigns patients with similar conditions into specific groups, but the payment methodologies used may vary across states and payers.

The following codes must be used in the hospital inpatient setting when billing for KYMRIAH and its administration:

- International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes
- International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes
- Revenue Codes
- National Drug Codes (NDCs)*
- Healthcare Common Procedure Coding System (HCPCS) Level II Codes*

*May be required by payers for inpatient claims.
CAR-T, chimeric antigen receptor T-cell.

Outpatient Setting

KYMRIAH may be paid for separately as a biologic in the outpatient setting. However, payment methodologies vary by payer. The following codes must be used in the outpatient setting when billing for KYMRIAH and its administration:

- ICD-10-CM Diagnosis Codes
- Revenue Codes
- NDCs*
- HCPCS Level II Codes
- Current Procedural Terminology (CPT®) Codes, including the Category I codes

*As required by Medicaid and other payers.

2 SECTION 2: DIAGNOSIS CODING

Hospital inpatient facilities use ICD-10-CM codes to report diagnoses. ICD-10-CM diagnosis codes identify why a patient needs treatment by documenting the medical necessity for administering KYMRIAH.

ICD-10-CM diagnosis codes are also used in the outpatient setting to report diagnoses. The codes identify why patients need treatment, such as KYMRIAH, and to classify diagnoses and conditions.

At least one ICD-10-CM diagnosis code is required on all claim forms. The diagnosis code selected should reflect the highest level of specificity available as documented in the patient's medical record.

The following diagnosis codes may apply in the inpatient and outpatient setting:

Patients Up to 25 Years of Age With B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) That Is Refractory or in Second or Later Relapse

ICD-10-CM Diagnosis Code[1]	Description[1]
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse
Z51.12[2]	Encounter for antineoplastic immunotherapy[2]

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

ICD-10-CM Diagnosis Code[1]	Description[1]
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C85.11–C85.19	Unspecified B-cell lymphoma
C85.81–C85.89	Other specified types of non-Hodgkin lymphoma
Z51.12[2]	Encounter for antineoplastic immunotherapy[2]

Adult Patients With Relapsed or Refractory (R/R) Follicular Lymphoma (FL) After Two or More Lines of Systemic Therapy

ICD-10-CM Diagnosis Code[1]	Description[1]
C82.00–C82.09	Follicular lymphoma grade I
C82.10–C82.19	Follicular lymphoma grade II
C82.30–C82.39	Follicular lymphoma grade IIIa
C82.40-C82.49	Follicular lymphoma grade IIIb
C82.80–C82.89	Other types of follicular lymphoma
C82.90–C82.99	Follicular lymphoma, unspecified
Z51.12[2]	Encounter for antineoplastic immunotherapy[2]

3 SECTION 3: INPATIENT PROCEDURE CODING

While ICD-10-CM diagnosis codes indicate why a patient needs treatment, ICD-10-PCS procedure codes report what services are provided during the hospital inpatient stay. Hospitals must report one of the following New Technology ICD-10-PCS procedure codes to report the administration of KYMRIAH.

ICD-10-PCS Procedure Code[3]	Description[3]
XW033J7	Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW043J7	Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7

4 SECTION 4: PRODUCT CODING

HCPCS Coding

HCPCS Level II codes help identify drugs, supplies, and medical procedures and services. KYMRIAH has been assigned the following unique Q-code (Q2042) to describe KYMRIAH when used in the outpatient setting for all approved indications. Although HCPCS codes are not typically used on inpatient claims, the National Uniform Billing Committee (NUBC) allows drug and biologic HCPCS codes on inpatient claims and some commercial payers may require them to be reported along with the revenue code (0891). All approved indications for KYMRIAH can be billed using Q2042. Please note, HCPs should contact third-party payers for specific information on their coding, coverage, and payment policies.

Payers	HCPCS Code[3]	Description[3]	Rationale
Commercial plans, Medicare, Medicaid, other government health plans	Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Medicare, Medicaid, and private payers may require this unique Q-code for hospital billing of KYMRIAH

If you have questions about HCPCS codes, please contact the appropriate commercial health plan or Medicare/Medicaid administrator.

NDC

In some cases, you also may be required to include the NDC number on the inpatient or outpatient claim. NDCs are universal product identifiers assigned to drugs upon FDA approval. Drugs and biologics, such as KYMRIAH, are assigned unique, 3-segment NDC numbers. Confirm NDC billing instructions with each payer, as requirements may vary.

Indication	10-Digit NDC Number[4]	11-Digit NDC Number[4]	WAC[5]
Pediatric and Young Adult Patients With R/R ALL	0078-0846-19	00078-0846-19	$605,404.01
Adult Patients With R/R DLBCL and FL	0078-0958-19	00078-0958-19	$523,151.79

FDA, US Food and Drug Administration; WAC, wholesale acquisition cost.

5 SECTION 5: CODING FOR CAR-T SERVICES

The American Medical Association (AMA) CPT manual instructions for Use of the CPT Codebook and Chapter 1 of the *Medicare National Correct Coding Initiative Policy Manual* recommend using the most specific CPT codes for autologous CAR-T therapy services, which are the Category I CAR-T CPT codes, as of January 2025. Category 1 CPT codes from the AMA are a temporary set of codes for emerging technologies, services, and procedures.

Hospitals may report these Category I CPT codes with the NUBC CAR-T revenue codes discussed in Section 6.

CPT Code[3]	CPT Description[3]
38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

Centers for Medicare & Medicaid Services (CMS) has recognized the intravenous administration of KYMRIAH as a separately payable service under the Outpatient Prospective Payment System (OPPS) with the assignment of 38228 to Ambulatory Payment Classification (APC) 5694.[6,7]

The other CAR-T Category I CPT codes (38225, 38226, 38227) are not separately payable services under OPPS and are considered to be included in the payment for Q2042 (KYMRIAH). Although there is no payment associated with CPT codes 38225, 38226, and 38227, these codes can still be reported to CMS for tracking purposes. This explanation was provided because of concerns raised about the old MLN Matters guidance (SE19009).[7]

Hospitals may report these charges with the new revenue and value codes established by the NUBC.

CMS provides specific guidance in article SE19009 on how best to report services related to CAR-T in various clinical scenarios. Please refer to the guidance for more information.

In addition, professional service payment is available under the Medicare Physician Fee Schedule (MPFS) for CPT 38228.[8] The payment rate is "carrier priced," which means the HCP must submit a letter to his/her Medicare Administrative Contractor (MAC).

The other codes (38225, 38226, and 38227) have status code "B," which means bundled services under the MPFS. This means the HCP is billing the code with another service, such as an evaluation and management service. For the two lab codes (38226 and 38227), there is likely no direct HCP involvement in performing the lab services other than ordering and supervising them.[7,9]

6 SECTION 6: REVENUE CODE REPORTING

Each line item on a CMS-1450 (UB-04) claim form must be accompanied by a revenue code. Revenue codes allow hospitals to capture cost data by a hospital department. Coding for revenue codes must follow the standards set by the NUBC, specific CMS guidance when applicable, and your institution's standard revenue coding practices, but not for physician offices reporting on the CMS-1500 claim form. On May 28, 2019, CMS discussed the use of these revenue codes and the reporting of hospital charges for cell collection, cell processing service, and the CAR-T product itself in both the outpatient and inpatient settings.[10]

The table below includes revenue codes from the NUBC 087x series for cell and gene therapy services and the 089x series for reporting the cell and gene therapy product. These codes are relevant to the administration of KYMRIAH in the inpatient or outpatient setting.[3]

This table also includes the corresponding Category I CPT codes discussed in Section 5. Payers may require certain combinations of revenue codes and HCPCS Level II or CPT codes to facilitate claims processing.

Revenue Code	Revenue Code Description[3]	HCPCS/ CPT Code	HCPCS/CPT Code Description[3]
0871[a]	Cell/Gene Therapy – Cell Collection	38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
0872[a]	Cell/Gene Therapy – Specialized Biologic Processing and Storage – Prior to Transport	38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
0873[a]	Cell/Gene Therapy – Storage and Processing after Receipt of Cells from Manufacturer	38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
0874	Cell/Gene Therapy – Infusion of Modified Cells	38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous
0891[b]	Special Processed Drugs – FDA Approved Cell Therapy	Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

[a] If collection occurs in the inpatient setting during the same stay as the administration of CAR-T, then MS-DRG 018 will be assigned based on the presence of a CAR-T administration ICD-10-PCS procedure code. If collection and cell processing to send to manufacturer are reported on an inpatient Medicare claim, report the date of service as the date of cell administration per SE19009 from CMS at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se19009.pdf[10]

[b] Medicare Special Edition article SE 19009 published May 28, 2019 updates information in the April 2019 OPPS Update Transmittal 4255 where CMS gives providers the option to include cell collection and cell processing charges with the product charge and report all under revenue code 0891. It can be found at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se19009.pdf . Value code 86 may be used to report product acquisition cost if requested or allowed by payers. Revenue code 0891 (an extension of pharmacy 025x or 063x) was created by the NUBC for reporting special processed drugs—FDA approved cell therapy and includes CAR-T products; see the NUBC manual for more details: https://www.nubc.org/system/files/media/file/2020/02/Cell-Gene%20Therapy%20Code%20Changes.pdf. All providers and payers have to use the new codes per the HIPAA transaction code set regulation. Additionally, providers should review the instructions released by CMS in Transmittal R10571CP, effective Oct 1, 2020, to better understand how to report certain instances when a CAR-T product is not incurred (such as expanded access use) as well as when a CAR-T product cost is incurred but the patient is involved in a clinical trial of some other drug. This can be found at: https://www.cms.gov/files/document/r10571cp.pdf.[11]

The coding information provided in this guide is gathered from various resources, is general in nature, and is subject to change without notice. The provider is responsible for determining the appropriate health care setting and submitting accurate claims for products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.

7 SECTION 7: VALUE CODE REPORTING

The value code fields allow for numeric expressions to be reported on inpatient or outpatient claims as applicable to each situation and may be required by payers. Numeric expressions can be integers, percentages, monetary amounts, and other values. Monetary amounts are right-justified with the cents added after the decimal delimiter.

Effective April 1, 2020, the NUBC designated value code 90 for Cell Therapy invoice cost.[12]

The actual invoice/acquisition cost from the KYMRIAH invoice is used as the amount. This value code is expected with the product charge reported with revenue code 0891. It may also be reported and/or payers may require it. Medicare does not require this value code but states that hospitals may use this value code to report acquisition costs on claims according to Transmittal 4255, Change Request 11216.[12]

Payers may be using this field to capture the acquisition cost of the product, rather than having HCPs provide a paper invoice. This process is expected to improve timely payment. Contact your major payers and claims clearinghouse to ensure their systems are accepting this code.

Value Code[12]	Invoice/Acquisition Cost[12]	Effective Date[12]
90	KYMRIAH invoice amount	April 1, 2020

8 SECTION 8: SAMPLE CMS-1450 CLAIM FORM FOR KYMRIAH

Completing the CMS-1450 (UB-04) Claim Form

Following treatment with KYMRIAH, a claim for reimbursement will be filed with the patient's health insurance plan. Services and supplies provided in the hospital for these procedures are billed using the CMS-1450 claim form.

The CMS-1450 claim form requires patient demographic information, insurance policy number, coded descriptions of services, National Provider Identifier (NPI), and revenue codes as needed. Most providers today are filing the CMS-1450 claim form electronically via the 837I format following Administrative Simplification Act (ASA) requirements rather than using the paper version. A sample CMS-1450 claim form is on page 11.

Important Reminders

When preparing claim submissions, keep the following in mind:

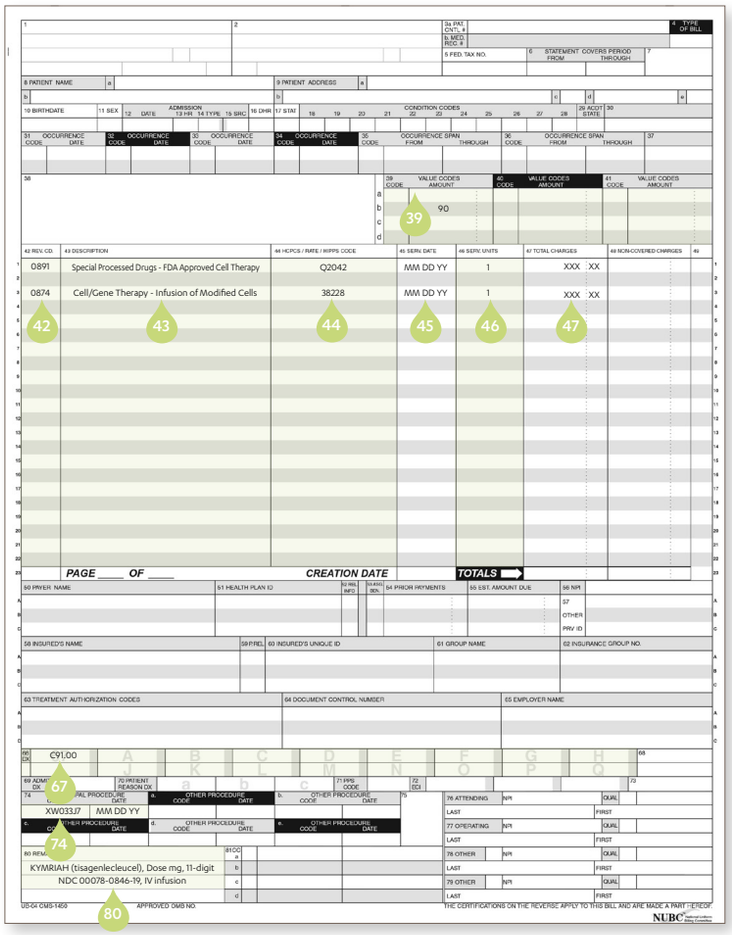
- Claims should be submitted in accordance with the ASA* requirements, taking into account the health insurance plan's submission guidelines
- Claims may need to be submitted using paper forms if additional documentation that cannot be submitted electronically is required
- To receive timely and appropriate reimbursement, claim forms should be completed fully and accurately, and submissions should address any additional medical necessity or prior authorization (PA) criteria

Claims Tips

- Use the correct billing codes in the correct sequence
  - Accurate coding is essential to ensure claims are processed and reimbursed promptly
  - Duplicative claims and claims that lack proper information are some of the top reasons why coverage is denied
  - Preferred codes may be provided by the health insurance plan during the benefits investigation process
  - CAR-T specific codes can be found on pages 5 to 9 and pages 12 to 13 of this guide
- Ensure all necessary PAs have been obtained
- Gather all of the documentation needed to support the claims process
  - Health insurance plans may require that claims be submitted with additional documentation such as:
    - Letter of medical necessity
    - Invoice for purchase of KYMRIAH
    - Prescribing information for KYMRIAH
    - Medical chart notes
- It is the sole responsibility of the HCP to select the proper codes, and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient

*To learn more about ASA, visit https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA.

Sample Annotated CMS-1450 (UB-04) Claim Form



39 **Field 39:** Enter the appropriate value codes and amounts, and ensure monetary values are right-justified and nonmonetary values are left-justified. If there is only 1 value code applicable to the claim, then the first field is populated – 39. There are 3 spots because more than 1 value code may be applicable or required to correctly bill the claim

42 **Field 42:** Enter the appropriate revenue codes corresponding to the HCPCS code in Field 44 (eg, 0891 for KYMRIAH and applicable codes for CAR-T services)[12]

43 **Field 43:** Enter the descriptions corresponding to the revenue codes in Field 42

44 **Field 44:** Enter the appropriate HCPCS/CPT codes and modifiers if applicable (eg, Q2042 for KYMRIAH and 38228 for CAR-T cell administration)[3]

45 **Field 45:** Enter dates of service

46 **Field 46:** Enter appropriate number of units of service (eg, Q2042 is a per therapeutic dose, so a "1" would be entered in this field)

47 **Field 47:** Enter total charges

67 **Fields 67 and 67A-67Q:** Enter the appropriate diagnosis code (eg, ICD-10-CM: C91.00 for acute lymphoblastic leukemia not having achieved remission or C83.31 for diffuse large B-cell lymphoma, lymph nodes of head, face, and neck)[1]
Note: *Other diagnosis codes often apply.*

74 **Field 74:** Enter principal ICD-10-PCS code (for example, XW033J7, introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7)[3]

80 **Field 80:** Enter drug-identifying information, as required by payer (eg, drug name, NDC 11-digit format, dosage, method of administration)
Note: *Additional information may also be electronically sent via attachment or other format, as allowed by the payer.*

Please see Important Safety Information on pages 21-23.
Click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

9 SECTION 9: SUMMARY OF APPLICABLE CODES FOR KYMRIAH

Code Set	Code	Description
ICD-10-CM Diagnosis Codes for Pediatric and Young Adult Patients With R/R ALL[1]	C91.00	Acute lymphoblastic leukemia not having achieved remission
	C91.02	Acute lymphoblastic leukemia, in relapse
	Z51.12	Encounter for antineoplastic immunotherapy[2]
ICD-10-CM Diagnosis Codes for Adult Patients With R/R DLBCL[1]	C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
	C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
	C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
	C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
	C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
	C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
	C83.37	Diffuse large B-cell lymphoma, spleen
	C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
	C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
	C85.11–C85.19	Unspecified B-cell lymphoma
	C85.81–C85.89	Other specified types of non-Hodgkin lymphoma
	Z51.12[2]	Encounter for antineoplastic immunotherapy[2]
ICD-10-CM Diagnosis Codes for Adult Patients With R/R FL[1]	C82.00–C82.09	Follicular lymphoma grade I
	C82.10–C82.19	Follicular lymphoma grade II
	C82.30–C82.39	Follicular lymphoma grade IIIa
	C82.40-C82.49	Follicular lymphoma grade IIIb
	C82.80–C82.89	Other types of follicular lymphoma
	C82.90–C82.99	Follicular lymphoma, unspecified
	Z51.12[2]	Encounter for antineoplastic immunotherapy[2]
Inpatient Procedure Coding[3]	XW033J7	Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
	XW043J7	Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7
Outpatient Product Coding[3]	Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
NDC[4]	0078-0846-19	Pediatric and Young Adult Patients With R/R ALL
	0078-0958-19	Adult Patients With R/R DLBCL and FL

Code Set	Code	Description
Category I CPT Codes[3]	38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
	38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
	38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
	38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous
Revenue Codes[3]	0871[a]	Cell/Gene Therapy – Cell Collection
	0872[a]	Cell/Gene Therapy – Specialized Biologic Processing and Storage – Prior to Transport
	0873[a]	Cell/Gene Therapy – Storage and Processing after Receipt of Cells from Manufacturer
	0874	Cell/Gene Therapy – Infusion of Modified Cells
	0891[b]	Special Processed Drugs – FDA Approved Cell Therapy
Value Code[12]	90	KYMRIAH invoice amount

[a] If collection occurs in the inpatient setting during the same stay as the administration of CAR-T, then MS-DRG 018 will be assigned based on the presence of a CAR-T administration ICD-10-PCS procedure code. If collection and cell processing to send to manufacturer are reported on an inpatient Medicare claim, report the date of service as the date of cell administration per SE19009 from CMS at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se19009.pdf[10]

[b] CMS allows other charges to be reported with this code in addition to the drug product. Check with payers to determine whether to use an HCPCS code with this revenue code.

SECTION 10: SAMPLE LETTERS

Three sample letters are available for illustrative purposes to support patient access to KYMRIAH treatment. They include:

- **Sample Medical Necessity Letter:** A template for the HCP to explain the rationale for why KYMRIAH is medically necessary for his or her patients
- **Sample Formulary Exception Letter:** A template for the HCP to request approval coverage for KYMRIAH when it is not on a health plan's formulary
- **Sample Appeal Letter:** A template for the HCP to submit an appeal and address the plan's reasons for coverage denial if an initial request for KYMRIAH is denied

It is the sole responsibility of the HCP to determine the appropriate letters to submit on behalf of patients and to ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please reach out to your representative for more information on these sample letters.

11 SECTION 11: FAQs

Q HOW ARE PAYERS TYPICALLY PROVIDING REIMBURSEMENT FOR KYMRIAH?

A Hospitals independently seek reimbursement for purchased products, services, and procedures related to the care of their patients. Some hospitals appear to be negotiating single-case agreements with commercial payers, which means that the reimbursement for KYMRIAH often varies by hospital, by payer, and possibly even by case.

For Medicaid, each state will have its own requirements. Requirements related to prior authorizations (PAs) are common among Medicaid, Medicare Advantage, and commercial payers, but there may be additional requirements for patient access to KYMRIAH. Medicaid-eligible persons may be covered by either Medicaid Fee-for-Service (FFS) or a Medicaid managed care plan; coverage and reimbursement may vary in these cases. Therefore, a Medicaid patient's benefits should be carefully confirmed.

Medicare inpatient reimbursement occurs under the Inpatient Prospective Payment System (IPPS) for participating hospitals (children's hospitals and dedicated cancer centers not included) using Medicare Severity-Diagnosis Related Groups (MS-DRGs). KYMRIAH is assigned to an MS-DRG, MS-DRG 018, that CMS created specifically for CAR-T cases. The base payment rate for CAR-T cases increased 16.8% to $314,231 for FY 2026.[13]

For CRS following CAR-T therapy, assign T80.82XA (initial encounter), T80.82XD (subsequent encounter), or T80.82XS (sequela), plus D89.83 (Cytokine release syndrome) as an additional code. These cases typically group to MS-DRGs 814, 815, or 816, depending on severity.[1,3]

For ICANS, ICD-10-CM does not provide a unique code. The most appropriate current option is G92.8 (Other toxic encephalitis), with 'code first' notes applying when due to a drug or toxin. Hospitals should follow payer-specific guidance until ICD-10-CM formally establishes a code for ICANS.[1]

It is important to note that a CRS case would only be assigned to MS-DRGs 814, 815, and 816 if the case was an admission that did not involve the administration of the KYMRIAH product. The same is true for an ICANS case assigned to MS-DRG 023, 024, 091, 092, or 093. If complications occur during the same inpatient stay during which KYMRIAH has been administered, the case would always group to MS-DRG 018.

Medicare outpatient reimbursement occurs under the hospital OPPS using Ambulatory Payment Classifications (APCs).[7]

Medicare Advantage plans may seek to reimburse for CAR-T therapy utilizing established plan contracts with hospitals, both for inpatient and outpatient reimbursement. Such a contract may be based on established Medicare FFS payment methodologies. However, each contract differs by payer and by the specific terms agreed to with the hospital providing CAR-T therapy.

Q WHAT PROCEDURE CODE SHOULD BE USED FOR THE INFUSION OF KYMRIAH?

A ICD-10-PCS procedure codes report what services were provided during a hospital inpatient stay, including the administration of drugs and biologics, such as KYMRIAH, in the inpatient setting. The procedure code is clinically and medically important to report, even though this is not considered a surgical procedure for purposes of an MS-DRG.

CMS has identified 2 procedure codes for the intravenous administration of KYMRIAH in an inpatient setting[3]:

- **XW033J7**, Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
- **XW043J7**, Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7

Patient cases involving KYMRIAH, as identified by procedure codes XW033J7 and XW043J7, are assigned to MS-DRG 018 (Chimeric Antigen Receptor [CAR] T cell and Other Immunotherapies)[3,*]

Q HOW MAY I BILL MEDICARE FOR OUTPATIENT SERVICES SINCE CODES 38225-38227 ARE ASSIGNED STATUS INDICATOR "B"?

A CMS explains the following in CMS Final Rule CMS-1809-FC, released November 27, 2024.

Although there is no payment associated with CPT codes 38225, 38226, and 38227, these codes can still be reported to CMS for tracking purposes. This explanation was provided because of concerns raised about the old MLN Matters guidance (SE19009).[7]

Therefore, in the CY 2025 final rule, CPT codes 38225, 38226, and 38227 are assigned to status indicator "B".[7] However, it will be possible for Medicare to track utilization and cost data from hospitals reporting these services, even for HCPCS codes reported for services in which no separate payment is made under the OPPS. Effective January 1, 2025, hospitals may report CPT codes 38225, 38226, and 38227 to allow for Medicare to track these services in those instances when the CAR-T drug is administered in the hospital outpatient setting. Hospitals will experience a line item rejection of these charges; the claim will be processed and other services will receive OPPS payment. In both instances, CPT 38228 would be reported for the administration of Q2042 for the drug/biological. Alternatively, the procedures described by 38225-38227, which represent various steps to collect and prepare the cells, may be reported together with the product charge reported under revenue code 0891. In contrast, when CAR-T cell preparation services are initiated and furnished in the outpatient setting, but the CAR-T cells are administered in the inpatient setting following inpatient admission to the hospital more than 3 days after the related outpatient services are furnished, the charges associated with the CAR-T cell dosing and preparation services as described by CPT codes 38225-38227 may be reported on the inpatient claim (bill type 11x) separately using revenue codes 0871, 0872, or 0873, or alternatively may be included in the charge reported for KYMRIAH using revenue code 0891. The date of CAR-T administration and the date of service on these cell collection and processing charges also need to be included.[3]

*Prior to October 1, 2021, KYMRIAH had been reported using 2 codes that were not product specific, XW033C3 and XW043C3. These codes are no longer the correct codes for KYMRIAH now that the product-specific codes are available.[14]
ASC, ambulatory surgical center.

Q CAN CELL COLLECTION BE PERFORMED IN-HOUSE, AND IF SO, HOW IS IT CODED?

A Cell collection can be performed at the hospital facility. Depending on the clinician's discretion and evaluation of the patient, it can be ordered and performed in either an inpatient or outpatient setting.[15]

If the cell collection is performed on an inpatient basis in the facility, it will be coded on the facility side either ICD-10-PCS code 6A550Z1 for the pheresis of leukocytes, single, or the code 6A551Z1 for the pheresis of leukocytes, multiple,[16] and on the professional side using CPT 38225 when personal services are documented.[3]

If performed on an outpatient basis, the charges for cell collection may be reported under revenue code 0871 with CPT 38225 for Medicare. If reported on an outpatient claim, the charges will result in a line-item rejection, but the claim will be processed. If the infusion occurs in the inpatient setting, the charges may be reported under revenue codes 0871 or 0891 according to CMS instructions in article CMS–1809–FC. Alternatively, the hospital may include the charges for these various steps in KYMRIAH product charge using revenue code 0891. Check with your non-Medicare payers on reporting requirements.[10]

Q WILL CELL COLLECTION BE PAID MORE THAN ONE TIME?

A The preparatory language in the CPT manual before the descriptions of the CAR-T Category I CPT codes 38225-38228 states that these "may only be reported once per day, regardless of the number of collections or quantity of cells collected."[17]

If it is medically necessary as determined by the clinician to perform cell collection over 2 or more days, then the clinician should order this for the patient. Documentation should support the services and the codes billed per dates of service following both the CPT manual and the payer's instructions.

Q WHAT HCPCS CODE SHOULD BE USED FOR KYMRIAH?

A HCPCS Level II codes help identify drugs, supplies, and medical procedures and services. A unique Q-code (Q2042) can be used to describe KYMRIAH when used in an outpatient setting.[3]

HCPCS codes are not usually reported on inpatient claims. However, commercial payers may require the HCPCS code to be reported under revenue code 0891 on inpatient claims to facilitate separate payment for the product.[11]

Hospitals or HCPs should contact payers for specific information on their coding, coverage, and payment policies.

KYMRIAH has only one HCPCS Level II code (Q2042), but in addition to reporting this, payers may require the NDC for the appropriate indication so they can provide appropriate reimbursement if they are doing indication-based payments. NDCs are universal product identifiers assigned to a drug upon US Food and Drug Administration (FDA) approval. Confirm NDC billing instructions with each payer, as requirements may vary. See the table on page 6 for the NDC numbers for KYMRIAH.

Q IS THERE A NATIONAL COVERAGE DETERMINATION FOR CAR-T THERAPY STILL IN PLACE?

A Yes, CMS's National Coverage Determination (NCD) for CAR-T cell therapy remains in effect. The policy was originally finalized on August 7, 2019 and implemented in September 2021. While the NCD was last revised in July 2025, the core coverage criteria remain unchanged except for the removal of the Risk Evaluation and Mitigation Strategy (REMS) requirement.[18,19]

Under the updated NCD, Medicare provides national coverage for FDA-approved CAR-T therapies when[18,19]:

1. The therapy is administered at a Medicare-enrolled healthcare facility, regardless of REMS enrollment status
2. The therapy is used for a medically accepted indication, meaning:
   - It is used according to the FDA-approved label, or
   - It is supported by 1 or more CMS-approved compendia

For more information and to view the full text of the final decision memo, visit https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291.

Q HOW ARE MEDICARE ADVANTAGE PLANS COVERING AND REIMBURSING CAR-T THERAPY?

A Medicare Advantage plans are utilizing previously established contractual terms with hospitals and providers for the payment of CAR-T therapy. Contracts may be based on Medicare FFS payment methodologies, but the exact terms will vary by contract.

Q HOW ARE OPPS PAYMENT RATES DETERMINED?

A Medicare's OPPS rate listed in Addendum B is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html. OPPS payment rates for drugs are based on the average sales price (ASP) information submitted by the manufacturer. ASP rates change quarterly and will not be the same as the previously quoted rate or the initial rate for KYMRIAH.

Q SINCE JANUARY 1, 2025, WHAT ARE THE CATEGORY I CPT CODES THAT PAYERS ARE ACCEPTING?

A For 2025, Medicare has assigned administration of CAR-T, CPT code 38228, a status indicator of "S," indicating its recognition of this service as a separately payable procedure. In the CMS–1809–FC, CMS explained that the administration of CAR-T therapy should be reported with 38228 and not chemotherapy, transplant, or unlisted codes.

Medicare has determined that hospitals can report CPT 38225 (collection/handling), 32226 (preparation for transport), and 32227 (receipt and preparation) to track these services when the CAR-T drug is administered in the outpatient setting. These steps are not paid separately under the OPPS; Medicare will reject them on an outpatient claim, or they may be included in the charge for the CAR-T product.[7] These codes may be reported with the CAR-T cell related revenue and value codes, as discussed in Sections 6 and 7. Contact third-party payers for specific information on their coding policies.

Q WHAT HAPPENED TO CPT CODES 0537T–0539T IN THE 2025 UPDATE? WHY WERE THE CODES CHANGED FROM CATEGORY III TO CATEGORY I?

A The codes 0537T-0539T have been deleted from CPT 2025. The Category III codes were replaced by Category I CPT codes 38225- 38228 (Cell collection, preparation, transportation and infusion of CAR- T cells).[3,7] The transition reflects the increased clinical use and acceptance of CAR-T cell therapy, warranting permanent Category I codes for standardized reporting and reimbursement.

Q WHEN ADMINISTERING KYMRIAH DURING AN OUTPATIENT VISIT, CAN I COMPLIANTLY BILL FOR THE NEW CATEGORY I CPT CODES (38225–38228) THAT DESCRIBE CELL COLLECTION AND PREPARATION, EVEN THOUGH HCPCS CODE Q2042 ALREADY INCLUDES THESE SERVICES

A For outpatient billing, CPT codes 38225-38228 may be reported to CMS for tracking purposes; however, they are not separately payable under OPPS. Q2042 should continue to be billed as the covered charge under revenue code 0891.[3,7]

Procedure codes align with revenue codes 0871-0874 for collection, processing, and infusion steps.[3]

Q WHAT SHOULD I DO IF A PAYER ISN'T READY TO USE THE CATEGORY I CPT CODES?

A It is important to have a discussion with the payer that the Category I CPT codes are part of the legal transaction effective January 1 of each year or ICD-10-CM code changes effective October 1 of each year.[2,7]

Furthermore, coding rules encompassed by the same ASA laws require reporting services accurately with the specific codes that describe the services performed on patients who are receiving CAR-T treatment. Therefore, it is important to report these codes. Payment for these services is a separate, albeit related, issue that is dependent on each payer's policies.

Q OF THE NEW CATEGORY I CPT CODES FOR CAR-T, WHICH ONES ARE TECHNICAL, PROFESSIONAL, OR BOTH? DO ANY MODIFIERS NEED TO BE USED?

A All of the new Category I codes are listed in the OPPS Addendum B. The technical or facility status indicators and payment rates are listed, as well as in the MPFS addenda for the professional status codes and payment rates.[20]

The 38225 for collection and 38228 for administration are both technical and professional codes. The 38226 and 38227 codes for the lab processing services have an MPFS indicator that is not expected to be billed with an office or nonfacility place of service (POS), so this means these services are recognized as technical services only to be billed by the facility performing the service.[10]

On December 9, 2025, CMS issued a formal transmittal that instructs MACs to discontinue the REMS and KX modifier requirement. Part B MACs shall no longer require modifier -KX to be appended to claims for CAR T-cell therapies. Part A MACs shall no longer require CAR T-cell therapy services to be submitted by or performed in an FDA REMS approved facility. This transmittal has an effective date of June 26, 2025, and an implementation date of February 6, 2026.[21]

There are no modifiers when the complete service is performed and documented. When codes are billed on a hospital claim with hospital revenue codes, by definition these would be the technical charges and codes. Some payers like to have the modifier "TC," and if so, it is okay to add as it is redundant.

See page 7 of this guide for more details about reporting and billing the Category III CPT codes for outpatient hospital services.

The coding information provided in this guide is gathered from various resources, is general in nature, and is subject to change without notice. The provider is responsible for determining the appropriate health care setting and submitting accurate claims for products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.

Please see Important Safety Information on pages 21-23.
Click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

Q WHAT IS THE VALUE CODE AND IS IT REQUIRED TO BE INCLUDED ON THE CLAIM FORM?

A The value code is a field on the CMS-1450 (UB-04) claim form that payers may elect to use to collect additional information from the provider. Effective April 1, 2020, the NUBC designated value code 90 for Cell Therapy invoice cost. Payers can elect to require providers to report the cost of CAR-T cells and/or other cellular and gene therapies using value code 90 so they can collect cost information electronically through the claims providers report. Since this is a voluntary rather than a mandatory field, HCPs should check with their payers about whether the field will be used. Medicare is not requiring this new value code, but states that hospitals may use this value code to report acquisition costs on claims.[12]

Medicare Plans: optional use of Value Code 90 (not required for payment).

Commercial Plans: may request Value Code 90, and some allow reporting with $0.00 when no product cost is incurred (eg, clinical trials or expanded access).

Q ARE THERE DIAGNOSIS CODES AVAILABLE FOR CYTOKINE RELEASE SYNDROME (CRS) AND IMMUNE EFFECTOR CELL ASSOCIATED NEUROTOXICITY SYNDROME (ICANS)?

A For patients who are diagnosed with CRS or ICANS, there are diagnosis codes available to code for the grade of CRS or for ICANS. For CRS, it is important to note that a case would only be assigned to MS-DRGs 814, 815, and 816 if the case was an admission that did not involve the administration of KYMRIAH. The same is true for ICANS; a case would only be assigned to MS-DRGs 023, 024, 091, 092, or 093 if the admission did not involve the administration of KYMRIAH. If complications occur during the same inpatient stay during which KYMRIAH has been administered, the case would always group to MS-DRG 018.

There are ICD-10-CM codes that identify that a patient has experienced a complication of immune effector cell therapy, and there are also codes that further specify the grade of either CRS or ICANS. As common complications of immune effector cell therapy, both CRS and ICANS have established diagnosis codes. There may be additional complications or signs of symptoms that may be relevant and should be coded.

To indicate that a patient has CRS and/or ICANS as a complication of KYMRIAH treatment, sequence first the appropriate code in the table below:

ICD-10-CM Diagnosis Code[3]	Description
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XD	Complication of immune effector cellular therapy, subsequent encounter
T80.82XS	Complication of immune effector cellular therapy, sequela

Then, code the appropriate complication and grade from the tables below:

Code[1]	Description[1]
D89.831	Cytokine release syndrome, grade 1
D89.832	Cytokine release syndrome, grade 2
D89.833	Cytokine release syndrome, grade 3
D89.834	Cytokine release syndrome, grade 4
D89.835	Cytokine release syndrome, grade 5
D89.839	Cytokine release syndrome, grade unspecified

Code[1]	Description[1]
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5

Q CAN MEDICARE BE BILLED FOR KYMRIAH ON A PROFESSIONAL CLAIM, WHEN KYMRIAH WAS ADMINISTERED IN A PHYSICIAN OFFICE OR INDEPENDENT CLINIC?

A Effective January 1, 2023, CMS will allow 11 (office) and 49 (independent clinic) to be used as valid POS for CAR-T cell claims. Therefore, Medicare providers will be able to bill for CAR-T cell product administered in the office and independent clinic settings of care.[21]

CMS notes that the CAR-T cell-related HCPCS codes (including Q2042 for KYMRIAH) cannot be processed in the current billing system for the office and independent clinic due to operational issues related to the limited field length for the dollar amount in the billing system. To overcome these operational challenges, CMS is dividing the total payment for the HCPCS code for the CAR-T cell product by 10 and the provider will have to bill in 0.1-unit fractions. Specifically, the provider will have to bill a total of 10 fractional units to reach the total Medicare-allowed payment amount for the CAR-T cell product. Depending on the Medicare-allowed payment, providers may be able to submit 5 separate claims, each for 0.2 units. Medicare will only pay up to 1 unit; anything exceeding 1 unit will be denied.[21]

For example, instead of billing 1 unit of QXXXX at $445,000.00, providers would bill:	
0.2 units	$89,000.06
0.2 units	$89,000.00
0.2 units	$88,999.99
0.2 units	$88,999.98
0.2 units	$88,999.97

These unique billing instructions do not affect billing for KYMRIAH in the outpatient setting of care, where providers will continue to bill 1 unit for the CAR-T cell product.[21]

In addition to the billing requirements above, providers must use 3 modifiers when billing for the CAR-T cell product in the office and independent clinic settings.[21] Please see the table below for more details.

Modifier	**Description**[21]
Modifier–LU	Fractionated payment CAR-T cell therapy
Modifier–76	Repeat procedure or service by same physician or other qualified HCP

Important Safety Information (continued)

Warnings and Precautions

Cytokine Release Syndrome: CRS, including fatal or life-threatening reactions, occurred following treatment with KYMRIAH. CRS occurred in 61 (77%) of the 79 pediatric and young adult patients with r/r ALL, including ≥ grade 3 (Penn Grading System) in 48% of patients. The median times to onset and resolution of CRS were 3 days (range: 1-22; 1 patient with onset after Day 10) and 8 days (range: 1-36), respectively. Of the 61 patients with CRS, 31 (51%) received tocilizumab. Ten (16%) patients received 2 doses of tocilizumab and 3 (5%) patients received 3 doses of tocilizumab; 17 (28%) patients received addition of corticosteroids (e.g., methylprednisolone).

CRS occurred in 85 (74%) of the 115 adult patients with r/r DLBCL receiving KYMRIAH, including ≥ grade 3 (Penn Grading System) in 23% of patients. The median times to onset and resolution of CRS were 3 days (range: 1-51; 1 patient with onset after Day 10) and 7 days (range: 2-30), respectively. Of the 85 patients with CRS, 19 (22%) received systemic tocilizumab or corticosteroids. Seven (8%) patients received a single dose of tocilizumab and 11 (13%) patients received 2 doses of tocilizumab; 11 (13%) patients received corticosteroids in addition to tocilizumab. One patient received corticosteroids for CRS without concomitant tocilizumab, and 2 patients received corticosteroids for persistent neurotoxicity after resolution of CRS.

CRS occurred in 51 (53%) of the 97 adult patients with r/r FL receiving KYMRIAH; all were grade 1 or 2 CRS (Lee Grading System). The median times to onset and resolution of CRS were 4 days (range: 1-14) and 4 days (range: 1-13), respectively. Of the 51 patients with CRS, 15 (29%) received systemic anticytokine treatment with tocilizumab. Three (6%) patients required 3 doses of tocilizumab, 4 (8%) patients required 2 doses and 8 (16%) patients required a single dose of tocilizumab. Two (4%) patients received corticosteroids in addition to tocilizumab.

Five deaths occurred within 30 days of KYMRIAH infusion. One patient with r/r ALL died with CRS and progressive leukemia, and 1 patient had resolving CRS with abdominal compartment syndrome, coagulopathy, and renal failure when an intracranial hemorrhage occurred. Of the 3 patients with r/r DLBCL who died within 30 days of infusion, all had a history of CRS in the setting of stable to progressive underlying disease, 1 of whom developed bowel necrosis.

Among patients with CRS, key manifestations included fever (93% r/r ALL; 85% r/r DLBCL; 92% r/r FL), hypotension (69% r/r ALL; 45% r/r DLBCL; 40% r/r FL), hypoxia (57% r/r ALL; 35% r/r DLBCL; 19% r/r FL), and tachycardia (26% r/r ALL; 13% r/r DLBCL; 2% r/r FL). CRS may be associated with hepatic, renal, and cardiac dysfunction, and coagulopathy.

Delay KYMRIAH infusion after lymphodepleting chemotherapy if patient has unresolved serious adverse reactions from preceding chemotherapies, active uncontrolled infection, active graft vs host disease, or worsening of leukemia burden.

Risk factors for severe CRS in the r/r ALL population are high pre-infusion tumor burden (>50% blasts in bone marrow), uncontrolled or accelerating tumor burden following lymphodepleting chemotherapy, active infections, and/or inflammatory processes. Confirm that a minimum of 2 doses of tocilizumab are available on-site prior to infusion of KYMRIAH. Monitor patients daily during the first week following KYMRIAH infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for at least 2 weeks after treatment with KYMRIAH. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care, tocilizumab, and/or corticosteroids as indicated.

Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Neurological Toxicities: Neurological toxicities, including severe or life-threatening reactions, occurred following treatment with KYMRIAH. Neurological toxicities occurred in 56 (71%) of the 79 patients with r/r ALL, including ≥ grade 3 in 22%. The median times to the first event and duration were 6 days from infusion (range: 1-301) and 7 days, respectively.

Neurological toxicities occurred in 69 (60%) of the 115 patients with r/r DLBCL, including ≥ grade 3 in 19%. The median times to the first event and duration were 5 days (range: 1-368) and 17 days, respectively.

Neurological toxicities occurred in 42 (43%) of the 97 patients with r/r FL, including ≥ grade 3 in 6%. The median times to the first event and duration were 8 days (range: 1-345) and 5 days, respectively.

Among patients who had a neurological toxicity, 84% occurred within 8 weeks following KYMRIAH infusion. Resolution occurred within 3 weeks in 71% of patients with r/r ALL, 50% of patients with r/r DLBCL, and 74% of patients with r/r FL. Encephalopathy lasting up to 70 days was noted. The onset of neurological toxicity can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

The most common neurological toxicities observed with KYMRIAH included headache (35% r/r ALL; 21% r/r DLBCL; 25% r/r FL), encephalopathy (30% r/r ALL; 16% r/r DLBCL; 3% r/r FL), delirium (19% r/r ALL; 5% r/r DLBCL; 1% r/r FL), anxiety (16% r/r ALL; 10% r/r DLBCL; 2% r/r FL), sleep disorders (11% r/r ALL; 10% r/r DLBCL; 6% r/r FL), dizziness (5% r/r ALL; 12% r/r DLBCL; 8% r/r FL), tremor (8% r/r ALL; 6% r/r DLBCL; 3% r/r FL), and peripheral neuropathy (4% r/r ALL; 12% r/r DLBCL; 7% r/r FL). Other manifestations included seizures and aphasia.

Please see additional Important Safety Information on pages 22-23.
Click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

Important Safety Information (continued)

Monitor patients daily during the first week following KYMRIAH infusion for signs and symptoms of neurological toxicities. Rule out other causes of neurological symptoms. Monitor patients for signs or symptoms of neurological toxicities for at least 2 weeks after infusion and treat promptly. Neurological toxicity should be managed with supportive care and/or corticosteroids as needed. Advise patients to avoid driving for at least 2 weeks following infusion.

Counsel patients to seek immediate medical attention should signs or symptoms of neurological toxicity occur at any time.

Hemophagocytic Lymphohistiocytosis (HLH)/ Macrophage Activation Syndrome (MAS): HLH/MAS, which can be life-threatening or fatal, has occurred following treatment with KYMRIAH. HLH was reported in 6% (5/79) of patients with r/r ALL (time to onset ranged from 3 to 18 days) and 2% (2/115) of patients with r/r DLBCL (times to onset were Day 7 and Day 10); all HLH events occurred during ongoing CRS and resolved. One patient (1%) with r/r FL developed HLH with a fatal outcome >1 year after receiving KYMRIAH. The patient did not have CRS during or immediately preceding HLH. Treatment of HLH should be administered as per institutional standards.

Hypersensitivity Reactions: Hypersensitivity reactions may occur with KYMRIAH. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide or dextran 40 in KYMRIAH. Observe patients for hypersensitivity reactions during and after the infusion.

Serious Infections: Infections, including life-threatening or fatal infections, occurred following treatment with KYMRIAH. Infections occurred in 57 (72%) of the 79 patients with r/r ALL; 38 patients (48%) experienced ≥ grade 3 infections, including fatal infections in 2 patients (3%); in 67 (58%) of the 115 patients with r/r DLBCL; 38 patients (33%) experienced ≥ grade 3 infections, including fatal infection in 1 patient (1%); and in 50 (52%) of the 97 patients with r/r FL; 20 patients (21%) experienced ≥ grade 3 infections, including fatal infection in 1 patient (1%). Prior to KYMRIAH infusion, infection prophylaxis should follow local guidelines. Patients with active uncontrolled infection should not start KYMRIAH treatment until the infection is resolved. Monitor patients for signs and symptoms of infection after treatment with KYMRIAH and treat appropriately.

Febrile neutropenia (≥ grade 3) was also observed in 34% of patients with r/r ALL, 17% of patients with r/r DLBCL, and 13% of patients with r/r FL after KYMRIAH infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids, and other supportive care as medically indicated.

In immunosuppressed patients, opportunistic fatal infections of the central nervous system including progressive multifocal leukoencephalopathy due to John Cunningham virus reactivation have occurred after KYMRIAH administration. Perform appropriate diagnostic evaluations in patients with neurological adverse events.

Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs directed against B cells. There is no experience with manufacturing KYMRIAH for patients with a positive test for HIV or with active HBV or active hepatitis C virus (HCV). Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

Prolonged Cytopenias: Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and KYMRIAH infusion. In patients with r/r ALL, ≥ grade 3 cytopenias not resolved by Day 28 following KYMRIAH treatment included neutropenia (40%) and thrombocytopenia (27%) among 52 responding patients. At 56 days following KYMRIAH, 17% and 12% of responding patients had ≥ grade 3 neutropenia or thrombocytopenia, respectively. In patients with r/r DLBCL, ≥ grade 3 cytopenias not resolved by Day 28 following KYMRIAH treatment included thrombocytopenia (39%) and neutropenia (25%) among 115 treated patients. In patients with r/r FL ≥ grade 3, cytopenias not resolved by Day 28 following KYMRIAH treatment included thrombocytopenia (17%) and neutropenia (16%) among 97 treated patients.

Prolonged neutropenia has been associated with increased risk of infection. Myeloid growth factors, particularly granulocyte-macrophage colony-stimulating factor, are not recommended during the first 3 weeks after KYMRIAH infusion or until CRS has resolved.

Hypogammaglobulinemia: Hypogammaglobulinemia and agammaglobulinemia related to B-cell aplasia can occur in patients after KYMRIAH infusion. Hypogammaglobulinemia was reported in 53% of patients with r/r ALL, 17% of patients with r/r DLBCL, and 18% of patients with r/r FL. Monitor immunoglobulin levels after treatment with KYMRIAH and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement standard guidelines.

The safety of immunization with live vaccines during or following KYMRIAH treatment has not been studied. Vaccination with live vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during KYMRIAH treatment, and until immune recovery following treatment with KYMRIAH.

Pregnant women who have received KYMRIAH may have hypogammaglobulinemia. Assess immunoglobulin levels in newborns of mothers treated with KYMRIAH.

Please see additional Important Safety Information on pages 21 and 23.
Click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

Important Safety Information (continued)

Secondary Malignancies: Patients treated with KYMRIAH may develop secondary malignancies or recurrence of their cancer. T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including KYMRIAH. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion and may include fatal outcomes.

Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Novartis Pharmaceuticals Corporation at 1-844-4KYMRIAH to obtain instructions on patient samples to collect for testing.

Drug Interactions

HIV and the lentivirus used to make KYMRIAH have limited, short spans of identical genetic material (RNA). Therefore, some commercial HIV nucleic acid tests may yield false positive results in patients who have received KYMRIAH.

Pregnancy, Lactation, Females and Males of Reproductive Potential

No data are available of KYMRIAH use in pregnant or lactating women. Therefore, KYMRIAH is not recommended for women who are pregnant or breastfeeding. A risk to the breastfed infant cannot be excluded. Pregnancy after KYMRIAH administration should be discussed with the treating physician. Pregnancy status of females of reproductive potential should be verified with a pregnancy test prior to starting treatment with KYMRIAH. Report pregnancies to Novartis Pharmaceuticals Corporation at 1-888-669-6682.

Adverse Reactions

The most common adverse reactions (>20%) reported in patients with r/r ALL were CRS, infections-pathogen unspecified, hypogammaglobulinemia, fever, decreased appetite, viral infectious disorders, headache, febrile neutropenia, hemorrhage, musculoskeletal pain, vomiting, encephalopathy, diarrhea, hypotension, cough, nausea, bacterial infectious disorders, pain, hypoxia, tachycardia, edema, fatigue, and acute kidney injury.

The most common adverse reactions (>20%) reported in patients with r/r DLBCL were CRS, infections-pathogen unspecified, fever, diarrhea, nausea, fatigue, hypotension, edema, hemorrhage, dyspnea, and headache.

The most common adverse reactions (>20%) reported in patients with r/r FL were CRS, infections-pathogen unspecified, fatigue, musculoskeletal pain, headache, and diarrhea.

Please see additional Important Safety Information on pages 21-22.
Click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

12 SECTION 12: KYMRIAH CARES™ SUMMARY OF SUPPORT RESOURCES

Patient Coverage and Treatment Support for KYMRIAH

KYMRIAH CARES is dedicated to providing personalized support throughout the KYMRIAH® (tisagenlecleucel) suspension for intravenous infusion treatment journey. We are your contact for ordering, tracking, and patient-related resources.

1. KYMRIAH Treatment Center Support

KYMRIAH CARES provides product-specific support, including managing and coordinating your orders related to KYMRIAH.

2. Patient Support

KYMRIAH CARES provides access to resources available for your patient.

3. Coordination of Care Support

KYMRIAH CARES provides information on KYMRIAH Treatment Center locations to HCPs who would like to learn more about KYMRIAH.

Contact Us for More Information

For information on KYMRIAH, coverage support, and patient assistance, call **KYMRIAH CARES** at **1-844-4KYMRIAH** (1-844-459-6742) Monday through Friday, 8 AM to 8 PM ET, or email kymriah.cares@novartis.com.

References: 1. Centers for Medicare and Medicaid Services. 2025 ICD-10-CM. Accessed July 22, 2025. https://www.cms.gov/files/zip/2025-code-tables-tabular-and-index-april.zip **2.** Centers for Medicare and Medicaid Services. 2025 ICD-10-CM Guidelines. Accessed July 22, 2025. https://www.cms.gov/files/document/fy-2025-icd-10-cm-coding-guidelines.pdf **3.** American Society of Transplantation and Cellular Therapy. ASTCT CAR-T therapy coding and billing guide. April 2025. Accessed July 22, 2025. https://www.astct.org/Portals/0/ASTCT_1579150-25_BillingandCodingQ2_Update.pdf **4.** Kymriah. Prescribing information. Novartis Pharmaceuticals Corp. **5.** Merative Micromedex. KYMRIAH®: Red Book product details. Accessed March 18, 2026. https://www.micromedexsolutions.com **6.** Department of Health and Human Services. Medicare and Medicaid programs. November 27, 2024. Accessed September 12, 2025. https://www.federalregister.gov/documents/2024/11/27/2024-25521/medicare-and-medicaid-programs-hospital-outpatient-prospective-payment-and-ambulatory-surgical **7.** Centers for Medicare and Medicaid Services. *Fed Regist*. 2025;(89)229:93912-94594. https://www.govinfo.gov/content/pkg/FR-2024-11-27/pdf/2024-25521.pdf **8.** Centers for Medicare and Medicaid Services. Physician fee schedule. Updated July 1, 2025. Accessed September 12, 2025. https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=3&H1=38228&M=5 **9.** Centers for Medicare and Medicaid Services. Status indicators. Accessed September 15, 2025. https://www.cms.gov/status-indicators **10.** American Society of Transplantation and Cellular Therapy. Coding options for CAR-T therapy services. April 2025. Accessed September 15, 2025. https://www.astct.org/Portals/0/4-1-2025%20ASTCT%20CAR-T%20Collection%20%26%20Processing%20Coding%20Options.pdf **11.** American Society of Transplantation and Cellular Therapy. Autologous CAR-T product reporting options. April 2025. Accessed July 22, 2025. https://www.astct.org/Portals/0/4-1-2025%20ASTCT%20CAR-T%20Administration%20Coding%20Options.pdf **12.** National Uniform Billing Committee. Summary of gene and cell therapy code changes. Accessed June 1, 2023. https://www.nubc.org/system/files/media/file/2020/02/Cell-Gene%20Therapy%20Code%20Changes.pdf **13.** Avalere. Accessed March 18, 2026. https://advisory.avalerehealth.com/insights/new-car-t-policies-affect-access-reimbursement. **14.** AAPC. CAR-T reimbursement requirements revamped again. Accessed September 12, 2025. https://www.aapc.com/blog/83771-car-t-reimbursement-requirements-revamped-again/?srsltid=AfmBOoomFwm_LXgSfVomOQb0viNmRW-D9qzun_zgo68e_8B4CGGb_onz **15.** Oluwole, Olalekan O. et al. Chimeric antigen receptor T-cell therapy in the outpatient setting: an expert panel opinion from the American Society for Transplantation and Cellular Therapy. Transplantation and Cellular Therapy. *Transplant Cell Ther.* 2024;30(2):131-142. **16.** Centers for Medicare and Medicaid Services. 2025 ICD-10-PCS code tables and index. https://www.cms.gov/files/zip/2025-icd-10-pcs-code-tables-and-index-updated-07/09/2024.zip **17.** Mitchell, A. 2025 CPT code changes for pathology. December 20, 2025. Accessed July 22, 2025. https://www.lighthouselabservices.com/2025-cpt-code-changes-for-pathology/#:~:text=Cellular%20and%20Gene%20Therapies%20involve,0540T%20which%20has%20been%20deleted **18.** Centers for Medicare and Medicaid Services. National drug determination 110.24. Accessed September 15, 2025. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 **19.** US Food and Drug Administration. FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor CAR T cell Immunotherapies. June 27, 2025. Accessed October 15, 2025. https://www.fda.gov/news-events/press-announcements/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor **20.** Centers for Medicare and Medicaid Services. July 2018 update of the hospital Outpatient Prospective Payment System (OPPS). MLN Matters number MM1078 revised. Accessed June 1, 2023. https://www.cms.gov/newsroom/fact-sheets/cms-proposes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center **21.** CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual. Transmittal 13432, Change Request 14204. *Removal of Chimeric Antigen Receptor (CAR) T-Cell Therapy and Risk Evaluation Mitigation Strategy (REMS) – NCD 110.24 and the "KX" Modifier for CAR-T Cell Therapy Claims*. Issued December 9, 2025. https://www.cms.gov/files/document/r13432cp.pdf

The coding information provided in this guide is gathered from various resources, is general in nature, and is subject to change without notice. The provider is responsible for determining the appropriate health care setting and submitting accurate claims for products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.

Please see Important Safety Information on pages 21-23.
Click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080