HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Kymriah (tisagenlecleucel)
BILLING CODE	Q2042
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Inpatient/Outpatient hospital
STATUS	Prior Authorization Required

Kymriah is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of: 1) Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse; and 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; and 3) Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (accelerated approval).

Kymriah (tisagenlecleucel) will be considered for coverage when the following criteria are met:

Acute Lymphoblastic Leukemia (ALL)

For **initial** authorization:

1. Member is 1 to 25 years of age; AND
2. Member has a diagnosis of relapsed or refractory B-cell ALL defined by **one** of the following:
   a) Second or greater relapse;
   b) Relapse after allogeneic stem cell transplantation (SCT);
   c) Primary refractory as defined by not achieving a complete remission (CR) after 2 cycles of a standard chemotherapy regimen or chemorefractory as defined by not achieving a CR after 1 cycle of standard chemotherapy for relapsed leukemia;
   d) Philadelphia chromosome positive (Ph+) ALL and intolerant to or have failed 2 lines of tyrosine kinase inhibitor (TKI) therapy [e.g. imatinib mesylate (Gleevec), dasatinib (Sprycel)];
   e) Ineligible for allogeneic SCT; AND
3. Documentation of CD19 tumor expression; AND
4. Bone marrow with ≥ 5% lymphoblasts by morphologic assessment; AND
5. Member does NOT have any of the following:
   a) Prior gene or CAR-T cell therapy
   b) Life expectancy less than 12 weeks; AND
6. Member has been pre-screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Kymriah REMS program
8. **Dosage allowed/Quantity limit:** Weight 50 kg or less: administer 0.2 to 5.0 x 10^6CAR-positive viable T cells per kg body weight intravenously. Weight above 50 kg: administer 0.1 to 2.5 x 10^8 total CAR-positive viable T cells (non-weight based) intravenously.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Kymriah will not be authorized for continued therapy.

Large B-cell Lymphoma

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Member has a diagnosis of relapsed or refractory large B-cell lymphoma including **one** of the following:
   a) Diffuse large B-cell lymphoma (DLBCL) not otherwise specified;
   b) High grade B-cell lymphoma;
   c) DLBCL arising from follicular lymphoma; AND
3. Member has received 2 or more lines of chemotherapy, including rituximab and anthracycline, and relapsed following autologous hematopoietic stem cell transplantation (SCT) or is not eligible for SCT; AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does NOT have any of the following:
   a) Active central nervous system malignancy involvement;
   b) Prior allogeneic HSCT;
   c) Prior CAR-T therapy (e.g. Yescarta); AND
6. Member has been pre-screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Kymriah REMS program.
8. **Dosage allowed/Quantity limit:** Administer 0.6 to 6.0 x 10^8 CAR-positive viable T cells.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Kymriah will not be reauthorized for continued therapy.

Follicular Lymphoma (FL)

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Member has a diagnosis of measurable relapsed or refractory follicular lymphoma (grade 1, 2, or 3A); AND
3. Member meets one of the following:
   a) Refractory to or relapsed within 6 months after completion of two or more lines of systemic therapy (including an anti-CD20 antibody and an alkylating agent)
   b) Relapsed during or within six months after completion of an anti-CD20 antibody maintenance therapy following at least two lines of therapy
   c) Relapsed after autologous hematopoietic stem cell transplant (HSCT); AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does NOT have any of the following:

a) Active central nervous system malignancy involvement
b) Prior allogeneic HSCT
c) Prior CAR-T therapy (e.g. Yescarta)
d) Follicular lymphoma grade 3B; AND

6. Member has been pre-screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Kymriah REMS program.
8. **Dosage allowed/Quantity limit:** Administer 0.6 to 6.0 x 10^8 CAR-positive viable T cells.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Kymriah will not be reauthorized for continued therapy.

HAP CareSource considers Kymriah (tisagenlecleucel) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/24/2017	New policy for Kymriah created.
08/27/2018	New indication of Large B-cell lymphoma was added. Criteria expanded for ALL diagnosis for member's disease history requirement.
08/18/2020	Updated billing code. Amended criteria for both diagnoses. ALL: changed lower age limit from 3 years to 1 year. Added #3, 4. Removed TKI's that were listed but not relevant in this context. B cell lymphoma: minor changes. Removed criterion for premedication. Removed some of the exclusion cut offs that appeared to be arbitrary to the controlled trial environment but not necessary to mandate from a utilization management perspective for the clinical setting.
05/27/2021	B cell lymphoma: Removed life expectancy restriction. Added ECOG score.
06/10/2022	Transferred to new template. Updated references. Added new indication for FL.

References:

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Effective date: 01/01/2025
Revised date: 06/10/2022