Updated: 03/2019
PARP Approved: 04/2019

Prior Authorization Criteria

Chimeric Antigen Receptor T cell (CAR-T) Immunotherapy

All requests for Chimeric Antigen Receptor T cell (CAR-T)* Immunotherapy require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

*CAR-T Immunotherapy medications include KYMRIAH™ and YESCARTA™. New products with this classification will require the same documentation.

For all requests for KYMRIAH™ and YESCARTA™ all of the following criteria must be met:

- Must have documentation of CD19 tumor expression;
- Must be prescribed by an Oncologist or Hematologist;
- Must be given as a one-time, single administration treatment;
- The member has received or will receive lymphodepleting chemotherapy within two weeks preceding infusion unless the member's WBC count is less than or equal to $1x10^9$/L within 1 week prior to infusion ;
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Exclusion criteria:
    - Will not be used as first-line therapy;
    - Will not be used in combination with other chemotherapy agents;
    - Will not be given as repeat treatment in individuals who have received CAR-T treatment previously.
    - Will not be given if the member has primary central nervous system (CNS) lymphoma

KYMRIAH™

Coverage may be provided with a diagnosis of B-cell acute lymphoblastic leukemia (ALL) and the following criteria is met:

- Member is up to 25 years of age
- Disease is considered refractory, or in second or later relapse, in *any* of the following scenarios:
    - Second or later bone marrow relapse;
    - Bone marrow relapse after allogeneic stem cell transplant;
    - Primary refractory or chemo-refractory after relapse;
    - Presence of > 5% blasts at screening
- For members with Ph+ ALL only:
    - Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to the following:
        - At least two tyrosine kinase inhibitors (TKIs)
- **Initial Duration of Approval:** 1 treatment

Coverage may be provided with a diagnosis of relapsed or refractory (r/r) large B-cell lymphoma and the following criteria is met:

- Member is 18 years of age and older
- Must be diagnosed with one of the following large B-cell lymphomas:
    - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified,
    - High grade B-cell lymphoma
    - DLBCL arising from follicular lymphoma.
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to the following:
    - Two or more lines of systemic therapy
- **Initial Duration of Approval:** 1 treatment

YESCARTA™

Coverage may be provided with a diagnosis of relapsed or refractory large B-cell lymphoma and the following criteria is met:

- Member is 18 years of age and older
- Must be diagnosed with one of the following large B-cell lymphomas:
    - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified,
    - Primary mediastinal large B-cell lymphoma,
    - High grade B-cell lymphoma,
    - DLBCL arising from follicular lymphoma.
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to the following:
    - Two or more lines of systemic therapy
- **Initial Duration of Approval:** 1 treatment

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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CHIMERIC ANTIGEN RECEPTOR T-CELL (CAR-T) IMMUNOTHERAPY PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

For Kymriah and Yescarta:

Does the member have CD19 tumor expression documentation? ☐ Yes ☐ No

Has the member received or will receive lymphodepleting chemotherapy within two weeks preceding the infusion?
☐ Yes ☐ No

Does the member have any of the following exclusions? Please mark if any apply. If NONE, leave blank.

☐ Medication will be used as first-line therapy
☐ Medication will be used in combination with other chemotherapy agents
☐ Medication will be given as repeat treatment in individuals who have received CAR-T treatment previously
☐ Medication will be given if the member has primary central nervous system (CNS) lymphoma

Kymriah only:

Does the member have a diagnosis of B-cell acute lymphoblastic leukemia (ALL)? ☐ Yes ☐ No

Is the disease considered refractory, or in second or later relapse, in *any* of the following scenarios? Please mark which applies:

☐ Second or later bone marrow relapse;
☐ Bone marrow relapse after allogeneic stem cell transplant;
☐ Primary refractory or chemo-refractory after relapse

For members with Ph+ ALL only: Has the member tried and failed or had an intolerance or contraindication to at least two (2) tyrosine kinase inhibitors (TKIs)? ☐ Yes ☐ No

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CHIMERIC ANTIGEN RECEPTOR T-CELL (CAR-T) IMMUNOTHERAPY
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests)

Kymriah only:
Has the member been diagnosed with relapsed or refractory (r/r) large B-cell lymphoma? ☐ Yes ☐ No

Has the member been diagnosed with one of the following large B-cell lymphomas? Please mark which applies.
☐ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified,
☐ High grade B-cell lymphoma
☐ DLBCL arising from follicular lymphoma.

Has the member tried and failed or had an intolerance or contraindication to two (2) or more lines of systemic therapy?
☐ Yes ☐ No

Yescarta only:
Does the member have a diagnosis of relapsed or refractory large B-cell lymphoma? ☐ Yes ☐ No

Has the member been diagnosed with one of the following large B-cell lymphomas? Please mark which applies:
☐ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified,
☐ Primary mediastinal large B-cell lymphoma,
☐ High grade B-cell lymphoma,
☐ DLBCL arising from follicular lymphoma

Has the member tried and failed or had an intolerance or contraindication to two (2) or more lines of systemic therapy?
☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date