Gateway Health℠ It's Wholecare.

Updated: 04/2021
PARP Approved: 06/2021

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™ (tisagenlecleucel), YESCARTA™ (axicabtagene ciloleucel), TECARTUS™ (brexucabtagene autoleucel) and BREYANZI ® (lisocabtagene maraleucel) and ABECMA (idecabtagene vicleucel). New products with this classification will require the same documentation.

For all requests for CAR-T Immunotherapy, all of the following criteria must be met:

- Must have documentation of CD19 tumor expression (excluding Abecma)
- 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
- Documentation screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing must be performed due to risk of viral reactivation
- 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 (excluding Abecma)

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 or submitted documentation) 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
- The member is diagnosed with any 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 or submitted documentation) 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
- The member is diagnosed with any 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 or submitted documentation) 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 with a diagnosis of relapsed or refractory follicular lymphoma (FL) and the following criteria is met:

- Member is 18 years of age and older
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims or submitted documentation) or had an intolerance or contraindication to the following:
  - Two or more lines of systemic therapy
- **Initial Duration of Approval:** 1 treatment

TECARTUS™

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

- Member is 18 years of age and older
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims or submitted documentation) or had an intolerance or contraindication to all of the following:
    - Anthracycline or bendamustine containing chemotherapy
    - An anti-CD20 antibody
    - A Bruton tyrosine kinase inhibitor (BTKi; ibrutinib or acalabrutinib)
- **Initial Duration of Approval:** 1 treatment

BREYANZI®

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
- The member is diagnosed with any of the following large B-cell lymphomas:
    - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma),
    - Primary mediastinal large B-cell lymphoma,
    - High grade B-cell lymphoma,
    - Follicular lymphoma grade 3B
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims or submitted documentation) or had an intolerance or contraindication to the following:
    - Two or more lines of systemic therapy
- **Initial Duration of Approval:** 1 treatment

ABECMA

Coverage may be provided with a diagnosis of relapsed or refractory multiple myeloma and the following criteria is met:

- Member is 18 years of age and older
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims or submitted documentation) or had an intolerance or contraindication to the following:
    - Four or more prior lines of therapy including:
        - an immunomodulatory agent
        - a proteasome inhibitor
        - an anti-CD38 monoclonal antibody
- **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℠ It's Wholecare.

Updated: 04/2021
PARP Approved: 06/2021

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:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, 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)

Diagnosis:	ICD Code:

For all CAR-T Therapy:

Does the member have CD19 tumor expression documentation (excluding Abecma)? ☐ Yes ☐ No

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

Is there documentation of screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing must be performed due to risk of viral reactivation? ☐ 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 (excluding Abecma)

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
☐ Presence of > 5% blasts at screening

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

Gateway Health℠ It's Wholecare.

Updated: 04/2021
PARP Approved: 06/2021

CHIMERIC ANTIGEN RECEPTOR T-CELL (CAR-T) IMMUNOTHERAPY PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 3

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:	Height:

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

Yescarta only:
Does the member have a diagnosis of relapsed or refractory follicular lymphoma (FL)? ☐ Yes ☐ No
Has the member tried and failed or had an intolerance or contraindication to two (2) or more lines of systemic therapy?
☐ Yes ☐ No

Tecartus only:
Does the member have a diagnosis of relapsed or refractory mantle cell lymphoma? ☐ Yes ☐ No
Has the member tried and failed or had an intolerance or contraindication to all of the following: anthracycline or bendamustine containing chemotherapy, an anti-CD20 antibody and a Bruton tyrosine kinase inhibitor (BTKi; ibrutinib or acalabrutinib)?
☐ Yes ☐ No

Breyanzi only:
Does the member have a diagnosis of relapsed or refractory large B-cell lymphoma? ☐ Yes ☐ No
Has the member been diagnosed with any of the following large B-cell lymphomas? Please mark which applies:
☐ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma)
☐ Primary mediastinal large B-cell lymphoma
☐ High grade B-cell lymphoma
☐ Follicular lymphoma grade 3B
Has the member tried and failed or had an intolerance or contraindication to two (2) or more lines of systemic therapy?
☐ Yes ☐ No

Gateway Health It's Wholecare.

Updated: 04/2021
PARP Approved: 06/2021

CHIMERIC ANTIGEN RECEPTOR T-CELL (CAR-T) IMMUNOTHERAPY
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 3 of 3

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:	Height:

MEDICAL HISTORY (Complete for ALL requests)

Abecma only:
Does the member have a diagnosis of relapsed or refractory multiple myeloma? ☐ Yes ☐ No
Has the member tried and failed or had an intolerance or contraindication to four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody?
☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date