MASSACHUSETTS

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CAR T-Cell Therapy Services for Multiple Myeloma (Idecabtagene Vicleucel) (Abecma) OR Ciltacabtagene Autoleucel (Carvykti) Prior Authorization Request Form #943

Medical Policy #942 Chimeric Antigen Receptor Therapy for Multiple Myeloma

CLINICAL DOCUMENTATION

- Clinical documentation that supports the medical necessity criteria for CAR T-Cell Therapy Services for Multiple Myeloma must be submitted.
- If the patient does not meet all the criteria listed below, please submit a letter of medical necessity with a request for Clinical Exception (Individual Consideration) explaining why an exception is justified.

Requesting Prior Authorization Using Authorization Manager

Providers will need to use Authorization Manager to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources

- Refer to our Authorization Manager page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form for CAR T-Cell Therapy Services for Multiple Myeloma (Idecabtagene vicleucel) (943) using Authorization Manager.

For out of network providers: Requests should still be faxed to 888-973-0726.

Patient Information	
Patient Name:	Today's Date:
BCBSMA ID#:	Date of Treatment:
Date of Birth:	Place of Service: Outpatient ❒ Inpatient ❒

Physician Information	**Facility Information**
Name:	Name:
Address:	Address:
Phone #:	Phone #:
Fax#:	Fax#:
NPI#:	NPI#:

Please check off if the patient is enrolled in a Clinical Trial.	
Clinical Trial #	❒

Please check off if the patient has the following diagnosis and HAS RELAPSED[A] or is REFRACTORY[B] :	
Documented diagnosis of multiple myeloma	❒

[A]Relapsed Multiple Myeloma
Relapse requires **1 or more** of the following direct indicators of increasing disease and/or end organ dysfunction that are considered related to the underlying plasma cell proliferative disorder.

1. Development of new soft tissue plasmacytomas or bone lesions
2. Definite increase in the size of existing plasmacytomas or bone lesions. A definite increase is defined as a 50% (and at least 1 cm) increase as measured serially by the sum of the products of the cross-diameters of the measurable lesion
3. Hypercalcemia (>11.5 mg/dL) [2.875 mmol/L]
4. Decrease in hemoglobin of >2 g/dL [1.25 mmol/L] or to <10 g/dL
5. Rise in serum creatinine by 2 mg/dL or more [177 µmol/L or more]
6. Hyperviscosity

Source: 2016 International Myeloma Working Group Uniform Response Criteria for Multiple Myeloma

[B]Refractory Multiple Myeloma
Refractory multiple myeloma is defined as documented progressive disease during or within 60 days (measured from the last dose) of completing treatment with the last anti-myeloma drug regimen.
Source: The Protocol of the pivotal KarMMa study

Progression is defined as an increase of ≥25% from the lowest response value in **any 1 or more** of the following:

- Serum M-component (the absolute increase must be ≥0.5 g/dL) and/or
- Urine M-component (the absolute increase must be ≥200 mg/24 hour) and/or
- Only in subjects without measurable serum and urine M-protein levels: the difference between involved and uninvolved free light chains levels (the absolute increase must be >10 mg/dL)
- Only in subjects without measurable serum and urine M-protein levels and without measurable disease by free light chains levels: bone marrow plasma cell percentage (the absolute percentage must be ≥10%)
- Definite development of new bone lesions or soft tissue plasmacytomas or definite increase in the size of existing bone lesions or soft tissue plasmacytomas
- Development of hypercalcemia (corrected serum calcium >11.5 mg/dL) that can be attributed solely to the plasma cell proliferative disorder.

Source: 2016 International Myeloma Working Group Uniform Response Criteria for Multiple Myeloma

Please check off that the patient meets ALL the following criteria:	
Adult (age ≥18) at the time of infusion	❒
Received adequate prior therapy including **ALL** of the following: • Immunomodulatory agent (such as thalidomide, lenalidomide, or pomalidomide) • Proteasome inhibitor (such as bortezomib, carfilzomib, or ixazomib), **AND** • Anti-CD38 monoclonal antibody (such as daratumumab or isatuximab).	❒
Has adequate organ and bone marrow function as determined by the treating oncologist/hematologist	❒
Does not have active infection(s) or inflammatory disorders, **AND**	❒
Has not received prior FDA-approved, BCMA directed, chimeric antigen receptor T therapy.	❒

CPT CODES/ HCPCS CODES/ ICD CODES

HCPCS codes:	Code Description	
C9399	Unclassified drugs or biologicals	❒
J3490	Unclassified drugs	❒
J3590	Unclassified biologics	❒
J9999	Not otherwise classified, antineoplastic drugs	❒
Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-	❒

	positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	
Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	❒

Providers should enter any <u>relevant diagnosis code(s)</u> below:

Code	Description	
		❒
		❒
		❒