

# DANA-FARBER CANCER INSTITUTE

Hematology-Oncology — Multiple Myeloma  
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February 01, 2026

Blue Cross Blue Shield  
Federal Employee Program  
Prior Authorization Department  
Medical Review Unit

## RE: Letter of Medical Necessity

Patient Name:	James O'Brien
Date of Birth:	1960-04-12
Member ID:	FEP456782134
Group Number:	FEP-STANDARD-2024
Medication Requested:	Ciltacabtagene autoleucel (Carvykti)
Diagnosis:	Multiple myeloma not having achieved remission (C90.00)

To Whom It May Concern:

I am writing on behalf of my patient, James O'Brien, to document the medical necessity of Ciltacabtagene autoleucel (Carvykti) for the treatment of Multiple myeloma not having achieved remission. This letter provides clinical documentation supporting the need for this medication and demonstrates that my patient meets the coverage criteria for this therapy.

## CLINICAL HISTORY AND DIAGNOSIS

65-year-old male with relapsed/refractory multiple myeloma, IgG kappa subtype, diagnosed December 2019. Has received 5 prior lines of therapy. Triple-class refractory (refractory to proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody). Specifically refractory to lenalidomide — progressed on lenalidomide maintenance after 14 months. Current M-protein rising at 2.8 g/dL with new lytic lesions on skeletal survey. ECOG 1.

## CURRENT DISEASE ACTIVITY

Most recent assessment (2026-01-15):

- Iss Stage: II
- Revised Iss Stage: II
- Ecog Performance Status: 1
- Disease Status: relapsed\_refractory
- Lines Of Therapy Completed: 5
- Refractory To: ['lenalidomide', 'pomalidomide', 'bortezomib']

## PRIOR TREATMENT HISTORY

The patient has tried and/or completed the following therapies:

- VRd (Bortezomib/Lenalidomide/Dexamethasone) (2020-01-15 to 2020-09-30)

Outcome: VGPR achieved. Transitioned to lenalidomide maintenance.

- Lenalidomide maintenance (2020-10-01 to 2021-12-15)

Outcome: Progressed after 14 months on lenalidomide maintenance. M-protein rose from 0.3 to 1.8 g/dL.

- Carfilzomib/Pomalidomide/Dexamethasone (KPd) (2022-01-10 to 2022-10-20)

Outcome: Partial response, then progressed at 10 months.

- Daratumumab/Bortezomib/Dexamethasone (DVd) (2023-01-05 to 2023-08-15)

Outcome: Partial response with 50% M-protein reduction. Progressed after 8 months.

- **Isatuximab/Carfilzomib/Dexamethasone (IsaKd)** (2023-11-01 to 2024-06-30)

Outcome: Minimal response only. Progressed after 8 months with new bone lesions.

- **Selinexor/Dexamethasone (Sd)** (2024-09-01 to 2025-02-28)

Outcome: Progressive disease with rising M-protein and new lytic lesions.

#### **MEDICAL NECESSITY SUMMARY**

Based on the clinical evidence presented, Ciltacabtagene autoleucel (Carvykti) is medically necessary for James O'Brien. The patient has a confirmed diagnosis of Multiple myeloma not having achieved remission (ICD-10: C90.00). Key criteria met: Multiple myeloma (ICD-10 C90.00) confirmed by bone marrow biopsy with 40% plasma cells; Patient is 65 years old ( $\geq 18$ ); Received bortezomib (VRd, DVd) and carfilzomib (KPd, IsaKd); Received lenalidomide (VRd, maintenance) and pomalidomide (KPd). I respectfully request approval of this prior authorization.

Please contact my office if you require any additional clinical information.

Sincerely,

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**Dr. Elizabeth Warren, MD, PhD**

Hematology-Oncology — Multiple Myeloma

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Date: 02/01/2026