

# Tremelimumab-actl (IMJUDO) in Hepatocellular Carcinoma (HCC)

## Criteria for Use

### Sept 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

### Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive tremelimumab.

- Autoimmune disease
- Immunosuppression including corticosteroid equivalent greater than 10 mg per day of prednisone
- Primary immunodeficiency
- History of allogeneic organ transplantation
- Untreated brain metastases
- Ascites requiring non-pharmacologic intervention in prior 6 weeks
- Hepatic encephalopathy in prior 12 months
- Uncontrolled systemic infection, including hepatitis B or C or known HIV
- Pregnancy
- Lactating

### Inclusion Criteria: All of the following criteria must be met

- Diagnosis of hepatocellular carcinoma
- No prior systemic therapy for Hepatocellular carcinoma (HCC), unless prior regimen discontinued premature due to intolerance
- Not a candidate to receive bevacizumab, therefore atezolizumab/bevacizumab regimen is not a 1L option
- Patient is able to receive durvalumab, in combination with tremelimumab
- Barcelona Clinic Liver Cancer stage B (not eligible for locoregional therapy) or stage C
- Child-Pugh score Class A

### Additional Inclusion Criteria

All of the following criteria must be met.

- Eastern Cooperative Oncology Group Performance Status 0 or 1
- Goals of care and role of Palliative Care Consult has been discussed and documented

### Additional Inclusion Criteria – Select if applicable

- For patients who can become pregnant: Pregnancy must be excluded prior to receiving tremelimumab.
- For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for three months after stopping treatment.