

Axatilimab-csfr (NIKTIMVO)

Criteria for Use

March 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

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 Formulary Committee 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 axatilimab.

- Weight less than 40 kg
- Known pregnancy
- Lactating

Inclusion Criteria

All of the following criteria must be met.

- Care provided by a VA or VA Community Care hematology provider
- Eastern Cooperative Oncology Group Performance Status 0 - 2
- Chronic graft-versus-host disease progression after at least 2 prior lines of systemic therapy *[that included ibrutinib, ruxolitinib and/or belumosudil, unless contraindicated]*

Additional Inclusion Criteria

- For females who can become pregnant: Pregnancy must be excluded prior to receiving axatilimab.
- For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 30 days after stopping treatment

Other Justification

Prepared: Jan 2026. Contact: B. Heron, Pharm.D., BCOP. National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)
