

Vedolizumab (ENTYVIO) Subcutaneous Injection in Inflammatory Bowel Disease Criteria for Use February 2025

Pharmacy Benefits Management Services and the VA 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.

Inclusion Criteria

- Had a clinical response after Week 6 following vedolizumab intravenous induction doses at Weeks 0 and 2 or is receiving intravenous doses of vedolizumab to maintain clinical remission.^{^1}

Footnotes

- 1 In the VISIBLE 1 UC trial, clinical response was defined as a reduction in total Mayo score of ≥ 3 points and $\geq 30\%$ from baseline with an accompanying decrease in rectal bleeding subscore of ≥ 1 point or absolute rectal bleeding subscore of ≤ 1 . In the VISIBLE 2 CD trial, clinical response was defined as a ≥ 70 -point decrease in Crohn's Disease Activity Index (CDAI) score from baseline.

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