

Entyvio® Intravenous (vedolizumab)

When requesting Entyvio® Intravenous (vedolizumab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or one of the off-label compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Entyvio Intravenous is indicated in adults for the treatment of:

- Ulcerative colitis, moderately to severely active disease.
- Crohn's disease, moderately to severely active disease.

Approved Off-label Compendial Uses

- Gastrointestinal toxicity associated with Checkpoint Inhibitor Therapy.
- Graft-Versus-Host Disease.

Coverage Guidelines

Crohn's Disease

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Entyvio Intravenous is prescribed by or in consultation with a gastroenterologist.

Ulcerative Colitis

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Entyvio Intravenous is prescribed by or in consultation with a gastroenterologist.

The individual must meet both of the following criteria for re-authorization (applies to both Crohn's disease and Ulcerative Colitis):

- Has been established on Entyvio therapy for at least 6 months (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Entyvio should be considered under initial criteria*);
- Meets one of the following:
 - Has experienced a beneficial clinical response in at least one objective measure compared to baseline (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR

- o Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or blood in stool).

Approval duration (initial and renewal): 12 months

Gastrointestinal Toxicity Associated with a Checkpoint Inhibitor Therapy

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Developed gastrointestinal toxicity while receiving a checkpoint inhibitor (*NOTE: Examples of checkpoint inhibitors are Keytruda [pembrolizumab intravenous infusion], Opdivo [nivolumab intravenous infusion], Yervoy [ipilimumab intravenous infusion], Tecentriq [atezolizumab intravenous infusion], Bavencio [avelumab intravenous infusion], Imfinzi [durvalumab intravenous infusion], and Libtayo [cemiplimab-rwlc intravenous infusion];*);
- Is symptomatic despite a trial of at least one systemic corticosteroid;
- Entyvio intravenous is prescribed by or in consultation with a gastroenterologist or an oncologist.

The individual must meet both of the following criteria for re-authorization:

- Has been established on Entyvio therapy for at least 6 months (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Entyvio should be considered under initial criteria;*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response in at least one objective measure compared to baseline (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR
 - o Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or blood in stool).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Graft-Versus-Host Disease

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Has acute graft-versus-host disease;
- Has tried at least one systemic medication for graft-versus-host disease (*NOTE: Examples of systemic medications include corticosteroids, antithymocyte globulin, cyclosporin, tacrolimus, mycophenolate mofetil, Jakafi [ruxolitinib], Simulect [basiliximab], an etanercept product, an infliximab product, sirolimus, Nipent [pentostatin], and a tocilizumab product;*);
- Entyvio intravenous is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

The individual must meet both of the following criteria for re-authorization:

- Has been established on Entyvio therapy for at least 1 month (*NOTE: A patient who has received less than 1 month of therapy or who is restarting therapy is reviewed under initial criteria*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response in at least one objective measure compared to baseline (e.g., improvement on endoscopic assessment, normalization of liver function tests, red blood cell count, platelet count, or resolution of fever or rash);
 - o Has experienced an improvement in at least one symptom, such as improvement in oral mucosal or gastrointestinal symptoms (e.g., diarrhea, nausea, vomiting, anorexia) or decreased fatigue compared to baseline.

Approval duration (initial): 1 month

Approval duration (renewal): 3 months

Dosing Recommendation

Crohn's Disease and Ulcerative Colitis

The recommended dose is 300 mg administered as an intravenous infusion at Week 0, Week 2, Week 6, then every 8 weeks thereafter.

Gastrointestinal Toxicity Associated with Checkpoint Inhibitor Therapy

The recommended dose is 300 mg administered as an intravenous infusion at Week 0, Week 2, Week 6, then every 8 weeks thereafter.

Graft-Versus-Host Disease

The recommended dose is 300 mg administered as an intravenous infusion at Week 0, Week 2, Week 6, then every 8 weeks thereafter.

References

1. Entyvio intravenous infusion [prescribing information]. Deerfield, IL: Takeda; February 2026.
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3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
4. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology*. 2021;160(7):2496-2508.
5. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.
6. The NCCN Management of Immunotherapy-Related Toxicities Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 14, 2025.
7. The NCCN Hematopoietic Cell Transplantation (HCT) Clinical Practice Guidelines in Oncology (version 2.2025 – June 5, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 14, 2025.

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9. Vermeire S, Loftus EV Jr, Colombel JF et al. Long-term Efficacy of Vedolizumab for Crohn's Disease. *J Crohns Colitis*. 2017 Apr 1;11(4):412-424.