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Provider Communications, RCR-A3W-04
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AUGUST 28, 2024

CHANGES TO VEDOLIZUMAB (ENTYVIO) UNDER THE MEDICAL BENEFIT

Dear Provider,

Vedolizumab (Entyvio) is on the **non-Medicare** list of office-administered drugs requiring prior authorization. **Effective December 1, 2024,** the criteria for intravenous vedolizumab (Entyvio) will be updated to reflect the preferred subcutaneous vedolizumab (Entyvio) for established members. In addition, subcutaneous vedolizumab (Entyvio) will **NOT** be covered under the medical benefit. Pharmacy benefit coverage remains available for members who meet prior authorization criteria. This change does not affect current authorizations for Entyvio; however, any new authorizations are subject to the criteria below. **This letter is a notification of the upcoming change in prior authorization criteria required before administering this medication under the medical benefit.**

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington, Options, Inc. (Kaiser Permanente) require prior authorization for a select group of injectable drugs that may be administered under the medical benefit in a physician's office or by home infusion. These reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Kaiser Permanente Pharmacy & Therapeutics Committee's evidence-based criteria for coverage.

BRAND NAME	GENERIC NAME	HCPCS
Entyvio	Vedolizumab intravenous	J3380
Entyvio	Vedolizumab subcutaneous	Unspecified

Prior Authorization Criteria for Vedolizumab (Entyvio) Products (changes in bold):

DRUG NAME	COVERAGE CRITERIA
VEDOLIZUMAB INTRAVENOUS	• Adult patients with moderately to severely active ulcerative colitis with contraindication, intolerance, or loss of response to at least one preferred TNF-inhibitor (infliximab-dyyb [e.g., Inflectra], adalimumab [e.g., Amjevita]) and subcutaneous vedolizumab*. It is recommended that the TNF-inhibitor should have been used in combination with azathioprine 6-mercaptopurine, or methotrexate. o **Established patients on intravenous vedolizumab must have a contraindication, intolerance, or loss of response to subcutaneous vedolizumab unless receiving infusions more frequently than every 8 weeks or patient has active disease.** • Adult patients with moderately to severely active Crohn's disease with: o Contraindication, or intolerance, to at least two TNF-inhibitors (infliximab-dyyb [e.g., Inflectra], adalimumab [e.g., Amjevita]), OR

DRUG NAME	COVERAGE CRITERIA
	○ Inadequate response with or loss of response to at least one preferred TNF inhibitor. ○ It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine, or methotrexate. Note: May be approved if patient is > 60 years old due to an increased risk of infection, or in patients with a history of malignancy. *Note: intravenous vedolizumab may be approved for 2 induction doses prior to subcutaneous use. Quantity Limit: 300 mg at 0, 2, and 6 weeks and then every 8 weeks thereafter. Dose escalation up to every 4 weeks may be considered medically necessary in patients who have had an inadequate response to every 8-week dosing. Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network* for medications impacted by this change.
VEDOLIZUMAB SUBCUTANEOUS	**Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following:** • **First dose for new starts to allow for self-administration training OR** • **Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND** • **Must meet clinical criteria below** • Adult patients with moderately to severely active ulcerative colitis with contraindication, intolerance, or loss of response to at least one preferred TNF inhibitor (infliximab-dyyb [e.g., Inflectra], adalimumab [e.g., Amjevita]). It is recommended that the TNF-inhibitor should have been used in combination with azathioprine 6-mercaptopurine, or methotrexate. • Adult patients with moderately to severely active Crohn's disease with: ○ Contraindication, or intolerance, to at least two TNF-inhibitors (infliximab-dyyb [e.g., Inflectra], adalimumab [e.g., Amjevita]), OR ○ Inadequate response with or loss of response to at least one preferred TNF inhibitor.

DRUG NAME	COVERAGE CRITERIA
	○ It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine, or methotrexate. Note: May be approved if patient is > 60 years old due to an increased risk of infection, or in patients with a history of malignancy.

**Site of Care: Infusion Therapy and Clinic Administered Medicines URL*
https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/infusion-site-care-policy.pdf

**Infused Drugs Restricted to Kaiser Permanente's Specialty Pharmacy Network URL*
https://healthy.kaiserpermanente.org/content/dam/kporg/final/documents/formularies/wa/infused-drugs-wa-en.pdf

Additional Information

A complete list of office-administered injectable drugs requiring prior authorization can be found on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/provider-manual/clinical-review/officeinject.

To request prior authorization review, please use the Referral Request online form (login required) located on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/provider-manual/clinical-review/preservice.

You can also fax your request to the Review Services department toll-free at 1-888-282-2685.

Thank you for the care you provide to our members, your patients. If you have any questions about this process, please call Review Services at 1-800-289-1363, Monday through Friday from 8 a.m. to 5 p.m.

Sincerely,

Ravi Ubriani, MD, Chair
Pharmacy & Therapeutics Committee