Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Vedolizumab Subcutaneous (Entyvio)

Notes:

- Quantity Limits: Yes
- ^Adequate trial is defined as the following:
 - o Biologics 12 weeks
- *If patient is vedolizumab naïve, prior authorization to take effect 4 weeks after approval date (2 loading dose intravenous infusions [given 2 weeks apart] required prior to maintenance with subcutaneous vedolizumab). If patient currently on intravenous vedolizumab maintenance, prior authorization to take effect immediately. Patient to transition to subcutaneous on next infusion due date.
- **Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation.

Initiation (new start) criteria: Formulary vedolizumab subcutaneous (Entyvio) will be

covered on the prescription drug benefit for <u>12 months*</u> when the following criteria are met:

- Prescriber is a gastroenterologist
- Patient has a diagnosis of ulcerative colitis or Crohn's disease
- Patient has failed an adequate trial[^], or patient has an allergy/intolerance^{**} to at least one of the following (or contraindication to both):
 - Infliximab product
 - Adalimumab product (criteria based)

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Formulary vedolizumab subcutaneous (Entyvio) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is a gastroenterologist
- Patient has a diagnosis of ulcerative colitis or Crohn's disease

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Formulary vedolizumab subcutaneous (Entyvio) will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Prescriber is a gastroenterologist
- Patient has responded to vedolizumab as determined by prescriber

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